REMARKS

Applicants submit that the present Amendment to the Specification, via a Substitute Specification, should be entered to correct formal matters related to the figure numbers. No new matter has been added.

Entry of the Amendment is proper under 37 CFR 1.312 because it is solely directed to correction of formal matters, without changing the scope of the claims. The Amendment was not presented earlier and was necessitated by the preparation of the Formal Drawings in accordance with Form PTO 948 and in compliance with 37 CFR 1.84.
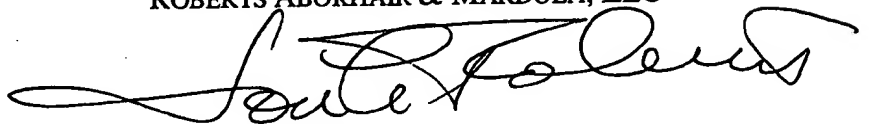
In preparation of the Formal Drawings, the multiple figures related Figures 1, 2, 4, 6, 8, 26, 31, 33, 34, 35, and 41 were designated with letters in accordance with 37 CFR 1.84. Additionally, to comply with the margin requirements, previously single Figures 21, 24, 25, 26, 26A, 27, 28, 29, 30, 33, and 34 were broken into multiple figures and designated with letters in accordance with 37 CFR 1.84.

These changes required corresponding changes in the specification, as shown in the attached "Marked-up Version" of the specification.

If there remain any issues that may be disposed of via a telephonic interview, the Examiner is kindly invited to contact the undersigned at the local exchange given below.

Respectfully submitted,

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3

Title: **System and Method for Providing Continuous, Expert Network Critical Care Services from a Remote Location(s)**

Inventor: **Brian A. Rosenfeld, M.D. and Michael Breslow**

Field of the Invention

This invention relates generally to the care of patients in Intensive Care Units (ICUs).

More particularly this invention is a system and method for care of the critically ill that combines a real-time, multi-node telemedicine network and an integrated, computerized patient care management system to enable specially-trained Intensivists to provide 24-hour/7-day-per-week patient monitoring and management to multiple, geographically dispersed ICUs from both on-site and remote locations.

Background of the Invention:

While the severity of illness of ICU patients over the past 15 years has increased dramatically, the level of and type of physician coverage in most ICUs has remained constant. Most ICU patients receive brief minutes of attention during morning rounds from physicians with limited critical care experience. During the remainder of the day and night, nurses are the primary caregivers, with specialists called only **after** patient conditions have started to deteriorate. The result of this mismatch between severity of illness and physician coverage is an unacceptably high ICU mortality rate (10% nationwide), and a high prevalence of avoidable errors that result in clinical complications. In 1998, an Institute of Medicine Roundtable determined that avoidable patient complications were the single largest problem in medical care delivery. In another prominent 1998 study of 1000 patients, 46% experienced an avoidable adverse event in care, with 40% of these errors resulting in serious disability or death.

The physicians who can remedy this situation are in critically short supply. Numerous studies have shown that Intensivists (physicians who have trained and board certified in Critical

1 Care Medicine) can markedly improve patient outcomes. However, only one-third of all ICU

2 patients ever has an Intensivist involved in their care, and the number of Intensivists would need

3 to increase tenfold (nationally) to provide 24-hour coverage to all ICU patients. With the rapid

4 aging of the population, this shortfall of expertise is going to increase dramatically.

5 Even where Intensivists are present (and especially where they are not), patients suffer

6 from unnecessary variation in practice. There is little incentive for physicians to develop and

7 conform to evidence-based best practices (it takes significant work and a change in behavior to

8 develop and implement them). This variation contributes to sub-optimal outcomes, in both the

9 quality and cost of care delivered to ICU patients.

10 What is needed is a redesigning of the critical care regimen offered to patients in an ICU.

11 Rather than the consultative model where a periodic visit takes place and the doctor then goes

12 away, a more active 24-hour intensivist managed care is required. Further, technology that

13 leverages the intensivists' expertise and standardizes the care afforded to patients in an ICU is

14 required. Further, continuous feedback to improve the practice of intensivists in an ICU is

15 necessary to provide the intervention required to minimize adverse events. This invention seeks

16 to provide new methods for managing and delivering care to the critically ill.

17 Attempts to automate various aspects of patient care have been the subject of various

18 inventions. For example, U.S. Patent No. 5,868,669 to Iliff was issued for "Computerized

19 Medical Diagnostic and Treatment Advice System." The disclosed invention is for a system and

20 method for providing computerized knowledge based medical diagnostic and treatment advice to

21 the general public over a telephone network.

22 U.S. Patent No. 5,823,948 to Ross, Jr. et al was issued for "Medical Records

23 Documentation, Tracking and Order Entry System". The disclosed invention is for a system and

1   method that computerizes medical records, documentation, tracking and order entries. A

2   teleconferencing system is employed to allow patient and medical personnel to communicate

3   with each other. A video system can be employed to videotape a patient's consent.

4   U.S. Patent No. 4,878,175 to Norden-Paul et al. was issued for "Method for Generating

5   Patient-Specific Flowsheets By Adding/Deleting Parameters." The disclosed invention is for an

6   automated clinical records system for automated entry of bedside equipment results, such as an

7   EKG monitor, respirator, etc. The system allows for information to be entered at the bedside

8   using a terminal having input means and a video display.

9   U.S. Patent No. 5,544,649 to David et al. was issued for "Ambulatory Patient Health

10 Monitoring Techniques Utilizing Interactive Visual Communications." The disclosed invention

11 is for an interactive visual system, which allows monitoring of patients at remote sites, such as

12 the patient's home. Electronic equipment and sensors are used at the remote site to obtain data

13 from the patient, which is sent to the monitoring site. The monitoring site can display and save

14 the video, audio and patient's data.

15 U.S. Patent No. 5,867,821 to Ballantyne et al. was issued for "Method and Apparatus for

16 Electronically Accessing and Distributing Personal Health Care Information and Services in

17 Hospitals and Homes." The disclosed invention is for an automated system and method for

18 distribution and administration of medical services, entertainment services, and electronic health

19 records for health care facilities.

20 U.S. Patent No. 5,832,450 to Myers et al. issued for "Electronic Medical Record Using

21 Text Database." The disclosed invention is for an electronic medical record system, which stores

22 data about patient encounters arising from a content generator in freeform text.

3

1   U.S. Patent No. 5,812,983 to Kumagai was issued for "Computer Medical File and Chart

2   System." The disclosed invention is for a system and method which integrates and displays

3   medical data in which a computer program links a flow sheet of a medical record to medical

4   charts.

5   U.S. Patent No. 4,489,387 to Lamb et al. was issued for "Method and Apparatus for

6   Coordinating Medical Procedures." The disclosed invention is for a method and apparatus that

7   coordinates two or more medical teams to evaluate and treat a patient at the same time without

8   repeating the same steps.

9   U.S. Patent No. 4,731,725 to Suto et al. issued for "Data Processing System which

10   Suggests a Pattern of Medical Tests to Reduce the Number of Tests Necessary to Confirm or

11   Deny a Diagnosis." The disclosed invention is for a data processing system that uses decision

12   trees for diagnosing a patient's symptoms to confirm or deny the patient's ailment.

13   U.S. Patent No. 5,255,187 to Sorensen issued for "Computer Aided Medical Diagnostic

14   Method and Apparatus." The disclosed invention is for an interactive computerized diagnostic

15   system which relies on color codes which signify the presence or absence of the possibility of a

16   disease based on the symptoms a physician provides the system.

17   U.S. Patent No. 5,839,438 to Chen et al. issued for "Intelligent Remote Visual Monitoring

18   System for Home Health Care Service." The disclosed invention is for a computer-based remote

19   visual monitoring system, which provides in-home patient health care from a remote location via

20   ordinary telephone lines.

1   U.S. Patent No. 5,842,978 to Levy was issued for "Supplemental Audio Visual

2   Emergency Reviewing Apparatus and Method." The disclosed invention is for a system which

3   videotapes a patient and superimposes the patient's vital statistics onto the videotape.

4   While these invention provide useful records management and diagnostic tool, none of

5   them provides a comprehensive method for monitoring and providing real time critical care at

6   disparate ICU's. In short, they are NOT designed for critical care. Further, none of these

7   inventions provide for the care of a full time intensivist backed by appropriate database and

8   decision support assistance in the intensive care environment. What would be useful is a system

9   and method for providing care for the critically ill that maximizes the presence of an intensivist

10   trained in the care of the critically. Further such a system would standardize the care in ICU's at

11   a high level and reduce the mortality rate of patients being cared for in ICU's

12   **Summary of the Invention:**

13   The present invention provides a core business of Continuous Expert Care Network

14   (CXCN) solution for hospital intensive care units (ICUs). This e-solution uses network,

15   database, and decision support technologies to provide 24-hour connectivity between Intensivists

16   and ICUs. The improved access to clinical information and continuous expert oversight leads to

17   reduced clinical complications, fewer medical errors, reduced mortality, reduced length of stay,

18   and reduced overall cost per case.

19   The technology of the present invention as explained below can be implemented all at

20   once or in stages. Thus the technology, as more fully explained below is available in separate

21   components to allow for the fact that hospitals may not be able to implement all of the

22   technology at once. Thus modular pieces (e.g. videoconferencing, vital sign monitoring with

1   smart alarms, hand-held physician productivity tools, etc.) can be implemented, all of which can

2   add value in a stand-alone capacity. First amongst these offerings will be an Intensivist Decision

3   Support System, a stand-alone software application that codifies evidence-based, best practice

4   medicine for 150 common ICU clinical scenarios. These support algorithms are explained more

5   fully below.

6   The "Command Center" model, again as more fully set forth below, will ultimately give

7   way to a more distributed remote management model where Intensivists and other physicians can

8   access ICU patients and clinicians (voice, video, data) from their office or home. In this

9   scenario, the present invention will be available in hospital applications that centralize ICU

10   information, and offer physicians web-based applications that provide them with real-time

11   connectivity to this information and to the ICUs. This access and connectivity will enable

12   physicians to monitor and care for their patients remotely. These products will be natural

13   extensions and adaptations of the present invention and the existing applications disclosed herein

14   that hose skilled in the art will appreciate and which do not depart from the scope of the

15   invention as disclosed herein.

16   The present invention addresses these issues and shortcomings of the existing situation in

17   intensive care, and its shortfalls via two major thrusts. First, an integrated video/voice/data

18   network application enables continuous real-time management of ICU patients from a remote

19   setting. Second, a client-server database application B integrated to the remote care network B

20   provides the data analysis, data presentation, productivity tools and expert knowledge base that

21   enables a single Intensivist to manage the care of up to 40 patients simultaneously. The

22   combination of these two thrusts B care management from a remote location and new,

23   technology-enhanced efficiency of Intensivist efforts B allows health care systems to

6

1   economically raise the standard of care in their ICUs to one of 24x7 continuous Intensivist

2   oversight.

3   It is therefore an object of the present invention to reduce avoidable complications in an

4   ICU.

5   It is a further object of the present invention to reduce unexplained variations in resource

6   utilization in an ICU.

7   It is a further objective of the present invention to mitigate the serious shortage of

8   intensivists.

9   It is yet another objective of the present invention to reduce the occurrence of adverse

10   events in an ICU.

11   It is a further objective of the present invention to standardize the care at a high level

12   among ICUs.

13   It is yet another objective of the present invention to reduce the cost of ICU care.

14   It is yet another objective of the present invention to dramatically decrease the mortality

15   in an ICU.

16   It is yet another objective of the present invention to bring information from the ICU to

17   the intensivist, rather than bring the intensivist to the ICU.

18   It is a further objective of the present invention to combine tele-medical systems

19   comprising two-way audio/video communication with a continuous real time feed of clinical

20   information to enable the intensivist to oversee care within the ICU.

21   It is a further objective of the present invention to allow intensivists to monitor ICUs

22   from a site remote from each individual ICU.

1   It is a further objective of the present invention to bring organized detailed clinical

2 information to the intensivist, thereby providing standardized care in the ICU.

3   It is yet another objective of the present invention to utilize knowledge-based software to

4 use rules, logic, and expertise to provide preliminary analysis and warnings for the intensivists.

5   The present invention comprises a command center/remote location, which is

6 electronically linked to ICUs remote from the command center/remote location. The command

7 center/remote location is manned by intensivists 24 hours a day, seven days per week. Each ICU

8 comprises a nurse's station, to which data flows from individual beds in the ICU. Each patient in

9 the ICU is monitored by a video camera, as well as by clinical monitors typical for the intensive

10 care unit. These monitors provide constant real time patient information to the nurse's station,

11 which in turn provides that information over a dedicated T-1 (high bandwidth) line to the ICU

12 command center/remote location. As noted earlier, the command center/remote location is

13 remote from the ICU, thereby allowing the command center/remote location to simultaneously

14 monitor a number of patients in different ICUs remote from the command center/remote

15 location. ,

16 At each command center/remote location, video monitors exist so that the intensivist can

17 visually monitor patients within the ICU. Further, the intensivist can steer and zoom the video

18 camera near each patient so that specific views of the patient may be obtained, both up close and

19 generally. Audio links allow intensivists to talk to patients and staff at an ICU bed location and

20 allow those individuals to converse with the intensivist.

21   Clinical data is constantly monitored and presented to the command center/remote

22 location in real time so that the intensivist can not only monitor the video of the patient but also

23 see the vital signs as transmitted from the bedside. The signals from the clinical data and video

1   data are submitted to a relational database, which comprises 1) standardized guidelines for the

2   care of the critically ill, 2) various algorithms to support the intensive care regimen, 3) order

3   writing software so that knowledge-based recommendations and prescriptions for medication can

4   be made based upon the clinical data, and 4) knowledge-based vital sign/hemodynamic

5   algorithms that key the intensivist to engage in early intervention to minimize adverse events.

6   The advantage of the present invention is that intensivists see all patients at a plurality of

7   ICU's at all times. Further, there is a continuous proactive intensivist care of all patients within

8   the ICU, thereby minimizing adverse events. Intervention is triggered by evidence-based data-

9   driven feedback to the intensivist so that standardized care can be provided across a plurality of

10   ICUs.

11   The economic benefits of the present invention are manifold. For the first time, 24-hour

12   a day, seven day a week intensivist care for patients in an ICU can be obtained. Further, more

13   timely interventions in the care of the patients can be created by the knowledge-based guidelines

14   of the present invention, thereby minimizing complications and adverse events. This in turn will

15   lead to a reduced mortality within the ICU, and hence, a reduced liability cost due to the

16   dramatic reduction in avoidable errors in health care.

17   By providing timely interventions, the length of stay within the ICU can be greatly

18   reduced, thereby allowing more critically ill patients to be cared for in the ICU.

19   In addition, by reviewing and standardizing the care afforded to patients in an ICU, a

20   more standardized practice across a variety of ICUs can be achieved. This will lead to more

21   cost-effective care within the ICU, and reduced ancillary cost for the care of the critically ill.

22   The overall architecture of the present invention comprises a "pod." The pod comprises a

23   tele-medicine command center/remote location connected to a plurality multiple ICUs at various

1   locations. The connection between the command center/remote location and the ICUs is via a

2   dedicated wide-area network linking the ICUs to the command center/remote location and a team

3   of intensivists who integrate their services to provide 24-hour, seven day a week care to all of the

4   pod ICUs.

5   The pod is connected via a wide-area network using dedicated T-1 lines, for example,

6   with redundant backup. This network provides reliable, high speed secure transmission of

7   clinical data and video/audio signals between each patient room and the command center/remote

8   location. The use of a T-1 line is not meant as a limitation. It is expected that more and higher

9   bandwidth networks will become available. Such high bandwidth networks would come within

10   the scope of the invention as well.

11   Each patient room is equipped with a pan/tilt/zoom video camera with audio and speaker

12   to enable full videoconferencing capability. In addition, computer workstations are dedicated for

13   exclusive physician use in each ICU, preferably at the nurse's station. Intensivists use the

14   workstations to view patient information, consult decision support information, record their

15   notes, and generate patient orders.

16   The patient management software used by intensivists is provided across the pod.

17   Updates and changes made to the record are available at both the ICU and the command

18   center/remote location for any given patient.

19   Each command center/remote location contains at least three workstations: one for the

20   intensivist, one for the critical care registered nurse, and one for a clerk/administrative person.

21   The intensivist workstation comprises separate monitors for displaying ICU video images

22   of patients and/or ICU personnel, output from bedside monitoring equipment, patient clinical

23   data comprising history, notes, lab reports, etc., and decision support information. The staff at

1 the command center/remote location are able to activate and control the cameras in each patient's

2 room so that appropriate visual views of the patient can be generated.

3 Intensivists are able to switch between rooms and patients and can monitor at least two

4 rooms simultaneously via the video screens. Patient data such as X-ray and ECG images are

5 scanned and transmitted to the command center/remote location upon request of the intensivist.

6 Remote patient management is utilized in the present invention's critical care program to

7 supplement traditional onsite care. The rationale underlying the remote patient management of

8 the present invention is that critically ill patients are inherently unstable and require continuous

9 expert care that is not now offered in existing ICU monitoring regimens. Further, remote

10 monitoring allows a single intensivist to care for patients in multiple ICU locations, thereby

11 creating an efficiency that makes continuous care feasible.

12 Remote intensivist care of the present invention is proactive. Intensivists will order

13 needed therapies and check results of tests and monitor modalities in a more timely fashion than

14 is currently offered. Patients can be observed visually when needed using the ceiling-mounted

15 cameras in each room.

16 Command center/remote location personnel communicate with ICU staff through

17 videoconferencing and through "hot phones," which are dedicated telephones directly linked

18 between the command center/remote location and the ICU. These communications links are

19 used to discuss patient care issues and to communicate when a new order has been generated.

20 Intensivists document important events occurring during their shift in progress notes

21 generated on the command center/remote location computer terminal.

1   Intensivists detect impending problems by intermittently screening patient data, including

2   both real time and continuously stored vital sign data. Patient severity of illness determines the

3   frequency with which each patient's data is reviewed by the intensivists.

4   **Brief Description of the Figures**

5   Figure 1A illustrates the logical data structure for billing, insurance and demographic

6   information.

7   Figure 1BA illustrates the logical data structure for billing, insurance and demographic

8   information (cont).

9   Figure 2A illustrates the command center logical data structure.

10   Figure 2BA illustrates the command center logical data structure (cont).

11   Figures 3 illustrates the logical data structure for creating a medical history.

12   Figure 4A illustrates the logical data structure for creating notes relating to patient

13   treatment and diagnosis.

14   Figure 4BA illustrates the logical data structure for creating notes relating to patient

15   treatment and diagnosis (cont).

16   Figure 4CB illustrates the logical data structure for creating notes relating to patient

17   treatment and diagnosis (cont).

18   Figure 5 illustrates the logical data structure for entry of medical orders.

19   Figure 6A illustrates the logical data structure for patient care, laboratory testing and

20   diagnostic imaging.

21   Figure 6BA illustrates the logical data structure for patient care, laboratory testing and

22   diagnostic imaging (cont).

1   Figure 7 illustrates the logical data structure for categories of information that are

2   permitted to be presented to intensivists and other care givers by the system.

3   Figure 8A illustrates the logical data structure for documenting patient vital signs.

4   Figure 8BA illustrates the logical data structure for documenting patient vital signs

5   (cont).

6   Figure 9 illustrates the distributed architecture of the present invention.

7   Figure 10 illustrates the system architecture of the present invention.

8   Figure 11 illustrates the decision support algorithm for decision support algorithm for

9   diagnosis and treatment of pancreatitis.

10   Figure 12 illustrates the vital signs data flow.

11   Figure 13A illustrates capture and display of diagnostic imaging.

12   Figure 13B illustrates establishing videoconferencing in the present invention.

13   Figure 14 illustrates the physician resources order writing data interface of the present

14   invention.

15   Figure 15 illustrates the physician resources database data interface of the present

16   invention.

17   Figure 16 illustrates the automated coding and billing system integrated with the

18   workflow and dataflow of the present invention.

19   Figure 17 illustrates the order writing data flow of the present invention.

20   Figure 18 illustrates the event log flow of the present invention.

21   Figure 19 illustrates the smart alarms implementation of the present invention.

22   Figure 20 illustrates the procedure note creation and line log for the present invention.

23   Figures 21A-B illustrates the acalculous cholecystitis decision support algorithm.

1   Figure 22 illustrates the adrenal insufficiency decision support algorithm.

2   Figure 23 illustrates the blunt cardiac injury decision support algorithm.

3   Figures 24A-B illustrates the candiduria decision support algorithm.

4   Figures 25A-B illustrates the cervical spine injury decision support algorithm.

5   Figures 26A-B illustrates the oliguria decision support algorithm.

6   Figures 26C-DA illustrates the oliguria decision support algorithm (cont).

7   Figure 26EB illustrates the oliguria decision support algorithm (cont).

8   Figures 27A-B illustrates the open fractures decision support algorithm.

9   Figures 28A-B illustrates the pancreatitis decision support algorithm.

10   Figures 29A-B illustrates the penicillin allergy decision support algorithm

11   Figures 30A-B illustrates the post-op hypertension decision support algorithm

12   Figure 31A illustrates the pulmonary embolism decision support algorithm

13   Figure 31BA illustrates the pulmonary embolism decision support algorithm (cont)

14   Figure 32 illustrates the seizure decision support algorithm

15   Figures 33A-B illustrates the SVT determination decision support algorithm

16   Figure 33CA illustrates the SVT unstable decision support algorithm

17   Figures 34A-B illustrates the wide complex QRS Tachycardia decision support algorithm

18   Figure 34CA illustrates the wide complex QRS Tachycardia decision support algorithm

19   (cont)

20   Figure 35A illustrates the assessment of sedation decision support algorithm

21   Figure 35BA illustrates the assessment of sedation decision support algorithm (cont)

22   Figure 36 illustrates the bolus sliding scale midazolam decision support algorithm

23   Figure 37 illustrates the sedation assessment algorithm decision support algorithm

1   Figure 38 illustrates the short term sedation process decision support algorithm

2   Figure 39 illustrates the respiratory isolation decision support algorithm

3   Figure 40 illustrates the empiric meningitis treatment decision support algorithm

4   Figure 41A illustrates the ventilator weaning decision support algorithm

5   Figure 41BA illustrates the ventilator weaning decision support algorithm (cont)

6   Figure 42 illustrates the warfarin dosing decision support algorithm

7   Figure 43 illustrates the HIT-2 diagnostic decision support algorithm

8 **Definitions of Terms and Data**

9   In the following Detailed description of the Invention, a number of modules and

10 procedures are described. For purposes of definitions, the following module definitions apply

11 and are more fully amplified in the descriptions of the figures that follow:

12 Term Definitions:

13   Following are a series of definitions for certain terms used in this specification:

14   Insurance carrier: This is a table of all the valid insurance carriers listed in the system of

15 the present invention.

16   Patient guarantor: Provides the insurance guarantor information for a given patient.

17   Patient information: Provides demographic information for each patient.

18   Medical event date history: This contains the various disorders of the patient and the

19 dates associated with major medical events relating to those disorders.

20   Medical history: Contains non-major system medical history of a patient.

21   Drug: Contains what medication and allergies have been identified for a patient at

22 admission.

23   Address: Contains the address or addresses for a given patient.

1   Patient visit: There may be multiple records for any given patient, since the patient may

2 visit the ICU on more than one occasion. This file contains a record of each visit to an ICU by a

3 patient.

4   Physician-patient task: Contains the task that had been defined for each patient.

5   Present illness: This contains a textural description of the patient illness for the specific

6 ICU visit.

7   Physical exam: This contains the information gathered as a result of a physical

8 examination of the patient during the admission to the ICU.

9   Surgical fluids: This provides all the information related to the fluids provided during

10 surgery.

11   Surgery: This contains all information pertaining to any surgical procedure performed on

12 a patient while the patient is at the ICU.

13   Patient admit: This provides general information that needs to be gathered when a patient

14 is admitted into the ICU.

15   Medical orders: This provides the general information for all types of medical orders

16 associated with a given patient.

17   Daily treatment: This contains the treatment provided for a given patient on a given day.

18   Daily diagnosis: This contains the daily diagnosis for a given patient, which includes

19 neurological, cardiological, pulmonary, renal, endocrinological, and any other diagnosis that may

20 be associated with a patient.

21   Vital sign information is also critical to the administration of care in the ICU. A number

22 of different modules collect information relating to patient vital signs. For example:

1   Patient admit: This provides the general information that needs to be gathered when a

2   patient is admitted to the ICU.

3   Patient visit: This contains a record of each visit to an ICU by a patient.

4   Patient: Provides demographic information for each patient.

5   Vital sign header: This contains general information related to the vital sign data for the

6   particular patient.

7   Vital sign: Contains the vital sign data taken at specific intervals for a given patient.

8   Hospital: This contains identifying information for a particular hospital where the care is

9   given.

10   ICU bed: Contains the association for identifying which beds are in a given ICU.

11   Command center/remote location definitions and modules have also been created for the

12   present invention to allow for the orderly storage and retrieval and entering of data. For

13   example:

14   Physician-physician (such as nurses and LPN and the like): Contains the names of all of

15   the physicians and physician extenders for the command center/remote location as well as for

16   ICUs associated with the command center/remote location.

17   Communication: Contains all of the various types of communication vehicles used to

18   contact an individual physician or physician extender.

19   Physician role: Contains the role a physician is playing for a given patient, (i.e., primary

20   care, consultant, etc.)

21   Patient: Provides demographic information for each patient.

22   Command center/remote location: Provides identifying information for a particular

23   command center/remote location.

1 Hospital: Contains identifying information for a particular hospital wherein an ICU is

2 located.

3 ICU: Contains identifying information for an ICU at a hospital.

4 ICU bed: Contains the association for identifying which beds are in a given hospital.

5 ICU patient location: Provides the association between an ICU and a patient and

6 identifies where a patient is located within an ICU in a particular hospital.

7 The order entry functionality of the present invention provides a critical service for

8 obtaining information on the patient during admission, medical orders, and procedures provided

9 to the patient during the ICU stay. For example:

10 Radiology: Contains all radiology performed on a particular patient.

11 Radiology results: Contains the results of each radiology test performed on the particular

12 patient.

13 Drugs: Contains all relevant information for all the drugs that a patient has been

14 administered.

15 Laboratory: Contains all laboratory tests ordered for a patient.

16 Microbiology result: Contains the results of microbiology organisms taken on a patient.

17 Laboratory result: Contains the results for a laboratory test ordered for a particular

18 patient.

19 **Detailed Description of the Invention**

20 The present invention is a system and method for remote monitoring of ICU's from a

21 distant command center/remote location. By monitoring a plurality of ICU's remotely,

22 intensivists can better spread their expertise over more ICU beds that heretofore achievable. The

1 presence of 24-hour a day/7 day-per-week intensivist care dramatically decreases the mortality

2 rates associated with ICU care.

3 Referring to Figures 1A and 1BA, the Billing and Demographic data structure of the

4 present invention is illustrated. Patient demographic information **9010** is collected on the

5 particular patient. This information comprises all the typical kinds of information one would

6 normally gather on a patient such as first name, last name, telephone number, marital status, and

7 other types of information. Patient insurance information **9012** is collected and associated with

8 the patient demographic information **9010**. Patient insurance information **9012** relates to

9 information on the type of accident and related information such as employment, employer

10 name, place of service, and other information that would relate to the accident that actually

11 occurred (if at all) and which would have to be reported to an insurance agency. This

12 information is associated with the patient demographic information which assigns the unique

13 patient ID to the particular patient.

14 Insurance plan information **9008** is also created and stored and comprises insurance

15 carrier ID's, the plan name, policy number, and group number. This information on the

16 insurance plan **9008** is also associated with the patient ID and demographic information **9010.**

17 Physician information **9002** is also created and stored for each physician associated with

18 the system of the present invention. Information such as first and last name, credentials, and

19 other information concerning the physician is saved. In addition, the physician's role is

20 identified **9004** and information concerning the physician and the physician's role is associated

21 with the particular patient via the patient ID stored in the demographic information **9010.**

22 Patient's are entered into the hospital by a hospital representative **9006** who has a

23 representative ID which also is ultimately associated with the patient ID. In addition,

1 communications data **9000** is stored concerning how a representative can be reached (cell phone,

2 home phone etc.).

3 Referring now to Figure 1BA, the Overall Billing and Insurance data structure is

4 illustrated. An insurance provider number **9014** is also stored in the system. Each physician is

5 given a provider number and provider ID by each insurance company. Thus data must be stored

6 regarding the ID that is given to a particular physician by each insurance provider. This

7 information is also stored and can be associated ultimately with treatment of the patient.

8 Each patient admitted to the hospital and to the ICU has a patient visit ID associated with

9 the patient **9017**. This visit ID has patient ID information, ICU information, admission date, and

10 other information relevant to the specific visit. This information is illustrated in Figure 1BA.

11 The visit ID **9017** is associated with the patient ID **9010** so that each visit can be tracked by

12 patient.

13 Insurance carrier information **9018** is stored by the system and is associated with the

14 insurance plan information **9008** as appropriate. Thus the particular insurance carrier with its

15 name, address, and other identifying information **9018** is associated with the type of plan **9008**

16 carried by the patient. The insurance carrier information **9018** together with the insurance plan

17 information **9008** is associated with the patient via the patient ID information **9010**.

18 Patient address information **9020** and **9022** are collected for each individual patient and

19 associated with the patient demographic information **9010**. If there is a patient guarantor, this

20 information is obtained and stored with information on the guarantor **9026**. Such information as

21 the guarantor's first and last name, date of birth, and other information is stored and is illustrated

22 in Figure 1BA. Further, the guarantor's address **9024** is also collected and ultimately associated

23 with the patient demographic information **9010**.

1   Referring to Figures 2A and 2BA, the Command Center logical data structure is

2   illustrated.

3   The various information associated with demographic and insurance information is again used to

4   manage the care and operations of the command center. Therefore, communications information

5   **9000** is combined with physician and physician extender (i.e. nurse, LPN and the like)

6   information **9002** and physician role **9004** to be associated with the demographic information

7   **9010.** The patient visit information **9017** together with this information is associated with the

8   patient's location which has a unique identifier **9030.** Each location ID has patient ID

9   information and visit ID information associated with it.

10   Referring now to Figure 2BA, the Command Center logical data structure illustration

11   continues. Each ICU bed has an associated location ID which comprises hospital ICU

12   information, room number, and bed number **9038.** In addition, and as described earlier,

13   instrumentation such as cameras are also associated with the particular patient. Therefore the

14   camera setting **9040** will have a location ID relating to the ICU bed as well as have camera value

15   settings and associated camera identifier information.

16   Each ICU bed **9038** is associated with an ICU **9032.** Each ICU has information

17   associated with it that uniquely identifies the ICU as being associated with the particular

18   hospital, and having particular phone numbers, fax numbers, work space addresses, and other

19   information, that help to identify the ICU.

20   As noted above, each ICU is associated with a hospital **9034.** Each hospital has a unique

21   identifier, as well as its own name, address, and other identifying information. Further, since

22   each hospital ICU is to be coordinated through a remote command center, information on the

23   remote command center **9036** is associated with the hospital information. Each command center

1   has a unique ID and has associated address information stored as well.

2   Thus in the Command Center logical data structure, patient ID information **9010** is linked

3   to a patient location **9030** which in turn is associated with an ICU bed **9038** each of which beds

4   are uniquely associated an ICU **9032** which is associated with a hospital **9034** which in turn has

5   the ICU managed by a command center **9036.**

6   An integral part of the system of the present invention is the recording of medical history.

7   Referring to Figure 3, the logical relationship among data elements for medial history is

8   illustrated. Patient visit information **9017** combined with the physician-physician extender

9   information **9002** is combined with specific note-taking information **9042.** The note information

10 comprises the date and time the notes are taken as well as the note type. The note ID is fed

11 information from the medical history item **9044,** which has its own unique medical ID associated

12 with it. This information comprises medical text, category of information, and other information

13 relevant to the medical history. As noted, this information for medical history **9044** is associated

14 with a note ID **9042,** which in turn is associated with the patient visit and physician information

15 **9017** and **9002.**

16   Referring to Figure 4A, 4BA, and 4CB, the note-keeping logical data structure of the

17 present invention is illustrated. As noted earlier, the note ID **9042** combines information from

18 visit ID, treating physician, and other information relating to the time the note was entered.

19 Other information is associated with the note ID. Referring first to Figure 4A, the patient visit

20 information **9017,** is associated with the note ID **9042.** Various procedural information **9046** is

21 kept by the system of the present invention and is associated with the visit ID **9017.** Physicians

22 are able to create free text patient illness notations **9048** and associate them with the note **9042.**

23 Similarly, free text information regarding functioning of the system **9050** is permitted and also

1   associated with notes regarding the particular patient and procedure 9042.

2   Specific notes regarding, for example, surgical procedures are also kept. Surgery notes

3   9054 are associated with a particular note ID and have such information as anesthesia, surgical

4   diagnosis, elective information, and other related surgical information. Surgical fluids 9052

5   administered during the course of surgery are associated with the surgery information 9054.

6   Additionally, any surgical complications 9056 are noted and also associated with the surgery

7   which in turn has an associated note ID.

8   Referring now to Figure 4BA, the logical data structure for notes and its description is

9   continued. An assessment plan 9058 is created and associated with the same note ID for the

10   particular patient. The plan has a free text field that allows a physician to create the appropriate

11   assessment plan and associate it with a note ID 9042.

12   Various daily notes are also kept and associated with the individual note ID 9042. For

13   example, the daily mental state 9060 is recorded to document the mental state of the patient. The

14   daily treatment 9062 administered to the patient is associated with the unique note ID. The daily

15   diagnosis 9068 is also created and associated with unique note ID 9042.

16   Any unstable conditions are also noted 9070 and records kept of those conditions.

17   Similarly mortality performance measures (MPM) information 9072 is kept and associated with

18   the unique note ID. To the extent that any physical exam 9074 is administered, that physical

19   exam and any free text created by the physician is associated with the unique ID and records

20   kept. Allergy information 9076 for the particular patient is also created and stored along with the

21   allergy type, and allergy name. This information is uniquely associated with the note ID.

22   Referring now to Figure 4CB, the Logical Data Structure for the Notes Creation and Storage

23   description is continued. A specific note item record 9078 is also kept and associated with

1 unique note ID. This note item comprises the principal diagnosis, the chief complaint, the past

2 history of the patient, the reason for the note, and various other identifications and flags of

3 information which help in documenting the patient's condition.

4 Any drugs that are administered to the patient, including dosage, type, and number **9086**

5 is kept and associated with the unique note ID **9042.**

6 Procedural note items are also documented **9082.** Procedural notes involve the

7 procedural type, the principal diagnosis, the procedural location, procedural indications, and

8 other information of a procedural nature. Procedural description information **9088** is kept as

9 input to the procedural note item. This information is also associated with a procedural

10 evaluation **9084** which comprises text describing the procedural evaluation that occurred, These

11 three items, the procedural description **9088**, procedural evaluation **9084**, and procedural note

12 items **9082**, are all uniquely associated with the note ID **9042.**

13 Referring now to Figure 5, the Logical Data Structure of the Medical Order Functionality

14 of the Present Invention is illustrated. Each medical order **9092** has a unique order ID associated

15 with it. This information derives its uniqueness from the visit ID, the representative ID, and

16 various information about the date in which the order was created and other such relevant

17 information. Any non-drug orders **9090** are associated with a unique non-drug order ID. The

18 order is classified, identified, and free text can be created by the physician to describe the order.

19 This information in the non-drug order **9090** is associated with the unique medical order for that

20 particular patient **9092.**

21 Again physician and physician extender identification information **9002** is also uniquely

22 associated with the medical order to identify the physician involved in creating the particular

23 order in question.

1   Drug orders **9094** are created each with its own unique drug order ID. Various

2   information is collected as part of the drug order including the type of drug, the dosage, start

3   date, frequency, stop date, to name but a few elements typical of a drug order. The drug order

4   information **9094** is associated with the unique medical order ID **9092** assigned to that particular

5   patient. All of the medical order information is associated with patient visit information **9017**

6   which allows that information to be uniquely identified with a particular patient for a particular

7   visit.

8   Referring again to Figure 4C~~B~~, the system is also capable of annotating and storing

9   various log items **9080**. For example, an event log item is given a number, a patient profile item

10   has its own number, as do neurological, cardiographic, pulmonary, renal, and other events can

11   have log items associated with them and may be used as input to any of the note taking of the

12   present invention.

13   Referring to Figure 6A and 6B~~A~~, the logical data structure of the patient care

14   functionality of the present invention is illustrated. Each patient visit with its unique ID **9017**

15   has a number of other pieced of information associated with it. For example, physician-patient

16   tasks are tracked **9098** and have a unique task ID associated with them. The patient code status

17   **9096** is documented and associated with the physician-patient task **9098** task ID. This

18   information is uniquely associated with the patient visit via the the patient visit ID **9017**.

19   Laboratory information **9100** has a unique lab ID associated with it. That information is

20   keyed to the visit ID and records the specimen taken, the date it was taken, and various other

21   information germaine to the laboratory procedure involved. Other lab procedures **9102** are also

22   documented with another unique ID. "Other" lab ID is associated with the laboratory ID **9100**

23   which again is uniquely associated with the particular patient.

1   Microbiological studies **9104** are documented together with the date and the date taken

2   and the type of study involved. Any study of microorganisms **9106** is documented with a unique

3   microorganism ID. Micro sensitivities **9108** which record the sensitivity to microorganisms and

4   certain antibiotics is recorded and associated with the microorganism ID **9106**. This information

5   in turn is associated with a microbiological study **9104**, all of which is associated with the unique

6   patient visit ID **9107**.

7   Respiratory studies **9101** are also recorded with unique identification numbers and a

8   description. This information is again associated with the patient visit ID **9017**.

9   Referring now to Figure 6BA, the logical data structure of the patient care functionality

10   of the Present Invention is further illustrated. Other organism studies **9118** are also conducted to

11   determine any other conditions associated with microorganisms that might exist with the

12   particular patient. This other organism information **9118** is associated with the microorganism

13   studies **9106** which in turn is associated with the microbiology category of information of the

14   present invention **9104**.

15   Various diagnostic imaging also takes place and is recorded. This image information

16   **9114** has unique image ID associated with each image and comprises associated information

17   such as the image type, the date performed, and other information relevant to the diagnostic

18   imagery. The result of the image taken **9116** is also uniquely identified with the image ID and a

19   unique image result ID. This information is associated with the image information **9114** which

20   again is uniquely associated with the patient visit ID.

21   Various intake and output for the patient's biological functioning is recorded **9110**.

22   Intake and output total **9112** is recorded and uniquely associated with the intake/output

23   identification note **9110**. Intake/output totals **9112** also comprised the weight the total taken in,

1   the total out, and five-day cumulative totals for biological functioning of the particular patient.

2   Referring to Figure 7, The Logical Data Structure Concern with Reference Information

3   for the present invention is illustrated. This data structure allows only certain ranges of data to

4   be input by care givers into the system. This is accomplished by having categories of

5   information **9120** each category capable of having only certain values. Similarly, each type of

6   data **9126** associated with each category is only permitted to have certain values. This

7   combination of Category and Type results in a Combined ID **9122** which can be used in

8   combination with certain values **9128** to create a value and combination **9124** that can be

9   presented to a care giver viewing and entering data. This effectively limits errors in data entry

10   by only allowing certain values to be entered for given types of data. For example, if only

11   milligrams of a medication are supposed to be administered, this data structure prevents a care

12   giver from administering kilograms of material since it is not a permitted range of data entry.

13   The "nextkey" function **9027** is the function that keeps track of the ID's that are given during the

14   administration of the present invention. This function insures that only unique ID's are given

15   and that no identical ID's are given to two different patient's for example.

16   Referring to Figure 8A, the Logical Data Structure of the Vital Signs Functionality of the

17   Present Invention is illustrated. Vital sign header information **9120** is created and uniquely

18   associated with the visit ID for the particular patient. This header information comprises a date-

19   time stamp combined with hospital information, medical reference numbers, and identification of·

20   the patient. Vital sign details **9122** are also created and uniquely date-time stamped and

21   associated with the particular visit ID for the patient. This information comprises all manner of

22   vital sign information relating to blood pressure, respiration, and other factors. Vital sign

23   information is associated with the patient visit **9017** and the demographic information concerning

1 the patient **9016.** Such associations of information can be the basis for later studies.

2 Referring to Figure 8BA, Additional Vital Sign Logical Data Structures are illustrated.

3 For example, a vital sign log header **9120** is created using the unique hospital ID and medical

4 record numbers. Other information such a patient name, and date-time stamp are also stored.

5 Vital sign log details **9124** are created and associated with the vital sign log header **9120.** For

6 example, blood pressure measurements, respiration, and other factors are all detailed for a

7 particular hospital ID. It should be noted that all vital sign data is logged in and kept by the

8 systems of the present invention. Where vital sign information is received but cannot be

9 associated with a particular patient, such communications are noted as errors.

10 Vital sign error details **9126** are also recorded and associated with a particular hospital.

11 Information and the vital sign error detail also comprises heart rate, blood pressure, and other

12 information. This information is associated with a vital sign error header **9130** which is

13 associated with the hospital identifier and the patient first and last name and other information.

14 Various vital sign error codes **9128** exist with the present invention and are used in association

15 with the vital sign error detail **9126.** This information however relates to communications of

16 vital sign data that are deemed "errors" as noted above.

17 Care Net patient location **9132** is recorded and associated with a particular hospital ID

18 and location ID for the particular patient. Carenet is a proprietary product designation of

19 Hewlett-Packard and is kept by the system of the present invention since it identifies the

20 equipment from which measurements come. The ICU bed information **9038** is associated with

21 the Care Net patient location **9132.**

22 Referring to **Figure 9,** the distributed architecture of the present invention is

23 shown. In concept, the distributed architecture comprises a headquarters component **200,** a

28

1   command center/remote location **202**, and a hospital ICU **204**, which, while represented as a

2   single hospital in this illustration, in the preferred embodiment comprises several hospital ICUs

3   at different locations. The headquarters unit **200** comprises a database server and data

4   warehouse functionality, together with a patient information front end. The patient information

5   front end **206** provides patient specific information to the command center/remote location. The

6   database server/warehouse function **208** comprises the amassed information of a wide variety of

7   patients, in their various conditions, treatments, outcomes, and other information of a statistical

8   nature that will assist clinicians and intensivists in treating patients in the ICU. The headquarters'

9   function also serves to allow centralized creation of decision support algorithms and a wide

10   variety of other treatment information that can be centrally managed and thereby standardized

11   across a variety of command center/remote locations. Further, the database server/data

12   warehousing functionality **208** serves to store information coming from command center/remote

13   locations replicating that data so that, in the event of a catastrophic loss of information at the

14   command center/remote location, the information can be duplicated at the command·

15   center/remote location once all systems are up and running.

16   At the hospital ICU **204**, each patient room **232, 234** has a series of bedside monitors and

17   both video and audio monitoring of each patient in the patient room. Each ICU further has a

18   nurse's station with a video camera and monitor **230** so that videoconferencing can go on

19   between the nurses and doctors at the nursing station and those intensivists at the command

20   center/remote location. The monitoring equipment at the ICU is served by a monitor server **236**,

21   which receives and coordinates the transmission of all bedside monitoring and nurses station

22   communication with the command center/remote location. Finally, each ICU has a patient

1 information front end **228**, which receives and transmits to the command center/remote location

2 information concerning the identity and other characteristics of the patient.

3   Command center/remote location **202** comprises its own video capture and monitoring

4 capability **212** in order to allow the intensivists to view the patients and information from the

5 bedside monitoring as well as to have videoconferencing with the nursing station and with

6 patients as the need arises. Information from the monitor server **236** at the hospital ICU is served

7 to an HL7 (the language for transmitting hospital/patient/diagnostic data) gateway **214** to a

8 database server **222**. In this fashion, information from the bedside monitors can be stored for

9 current and historical analysis. Monitor front ends **216** and **218** allow technicians and command

10 center/remote location personnel to monitor the incoming data from the patient rooms in the

11 ICU. Information from the patient information front end **228** is provided to an application server

12 **224**, having its own patient information front end **226** for aggregating and assembling

13 information in the database **222** that is associated with individual patients in the ICU.

14   It is expected that there will be a great deal of concurrent hospital data that is necessary to

15 the implementation of the present invention. It is therefore expected that there will be a legacy

16 database system **210** having a front end **220** from which intensivists and command center/remote

17 location personnel can retrieve legacy database information.

18   Referring to **Figure 10**, a system architecture of one embodiment of the present invention

19 is illustrated. Headquarters **200** comprises an application server **238**, an NT file server **240**, and

20 Sun SPARC Enterprise 250 **242** and Enterprise network management system **244**, a Cisco 3600

21 router **246**, a Cisco 2924 switch **248**, and a hot phone **250**. The application server **238** is

22 designed to monitor and update those applications used at the command center/remote location.

23 The NT file server serves to monitor, store, and replicate information coming from the command

30

1   center/remote locations. The SPARC Enterprise 250 server **242** is a disc storage server, for

2   storing and serving information, such as practice guidelines, algorithms, patient information, and

3   all matter of other information records that must be stored in order to support the present

4   invention. As explained below, the SPARC Enterprise 250 server and other components are such

5   as routers and switches are commonly used in the ICU, the command center/remote location, and

6   the headquarters. For example:

7   The Cisco 3600 router is a multi-function device that combines dial access, routing, and

8   local area network (LAN) to LAN services, as well as the multi-service integration of voice,

9   video, and data in the same device. This is necessary, since the various command center/remote

10   locations, headquarters, and intensive care units all must integrate and transmit video, audio, and

11   data among the various entities.

12   The Cisco 7204 is a router which provides high speed LAN interconnect, virtual private

13   networks, and Internet access, all of which is required for providing the communication in the

14   network of the present invention; and

15   The Cisco 2924 switch is an autosensing fast ethernet switch, allowing networked

16   multimedia and virtual LAN support. Multi-level security is also offered in the switch to prevent

17   unauthorized users from gaining access and altering switch configuration. These components are

18   also identified in the figures (below).

19   The particular commercial systems named here are given as but some examples of

20   equipment available today. The function of these equipment is the important factor. Other

21   similar or improved equipment can also be utilized.

22   The network management system **244** allows the entire traffic and condition of the

23   network to be monitored and to allow maintenance to take place. The router **246** and switch **248**

31

1   is used for communication with the various command center/remote locations that are served by

2   the Headquarters component. The Headquarters component interacts via frame relay with the

3   command center/remote location 202.

4   Command center/remote location 202 comprises an applications server 262 for the

5   purpose of running various applications for the intensivists and command center/remote location

6   staff. The NT file server 264 at the command center/remote location allows patient files,

7   historical files, algorithms, practice standards, and guidelines, to be served to the clinicians and

8   intensivists to assist in monitoring the patients. The Sun SPARC Enterprise 250 266 is used to

9   for storage purposes as noted above. The Enterprise network management system 268 monitors

10   the overall health of the network of command center/remote locations and intensive care units as

11   well as the functionality of the individual pieces of equipment within the command

12   center/remote location. A Cisco 2924 switch 256 and Cisco 7204 router 258, combined with the

13   Cisco 3600 router 260 allows for point to point communication over a T1 line, with a plurality of

14   intensive care units located remotely from the command center/remote location. Hot phones 252

15   and 254 allow communication with the headquarters and the intensive care unit.

16   Intensive care unit 204 comprises a Cisco 2924 switch 272 for the purpose of interfacing

17   with the various audio-video feeds 274, 276 from the various patient rooms and the nursing

18   station. A local work station 280 is connected to a scanner 282 which allows data to be input,

19   scanned, and communicated via the point to point T1 communications to the command

20   center/remote location. Further, the workstation 280 provides for textual advice and patient

21   orders to be delivered to the intensive care unit for execution. The intensive care unit also

22   comprises a laser printer 284 for the printing of patient orders and other information relevant to

23   the care of intensive care patients.

1   Referring to **Figure 11,** the videoconferencing/surveillance/imaging components of the

2   present invention are illustrated. The hospital ICU **204** comprises a series of video cameras **290,**

3   which are located in patient rooms and at the nurse's station. Control for the cameras is provided

4   through an RS424 to RS232 converter **288,** with instructions for imaging emanating from the

5   workstation at the command center/remote location **252** through the ICU workstation **280**

6   through a multi-port serial controller **286.** Video feed from the video cameras **290** is provided to

7   an audio-video switcher **292,** which in turn provides its output to the multi-port serial controller

8   **286** for subsequent viewing at the nurse's station and at the command center/remote location. Of

9   equal importance is a microphone feed from the patient and from the nurses. That microphone

10   **296** provides its signal to an audio line amplifier **294,** which in turn provides an audio feed to the

11   audio-video switcher **292.** In this way, a patient can provide information, as can nurses who are

12   visiting the patient during the course of patient care. It is also important that information of an

13   audio nature be fed to the intensive care unit, both to the patient rooms and to the nurse's station.

14   To do this, the multi-port serial controller **286** provides an audio signal to a reverse audio

15   switcher **298,** which in turn provides information to speakers **300** that are located at the nurse's

16   station as well as at the bedside of the patients. Information to the reverse audio switcher is

17   provided an audio amplifier **302** from information from a video codec **304,** which in turn is

18   connected to the workstation at the ICU. As noted earlier, a scanner **282** is provided, so that

19   information can be scanned and provided to the command center/remote location **202** and a hot

20   telephone **278** communicates with a telephone **252** at the command center/remote location.

21   Referring to **Figure 12** the vital signs data flow is illustrated. The monitoring system at

22   each ICU bedside comprises a monitoring system for monitoring the vital signs for the patient.

23   The vital sign monitoring system **450** captures vital sign data **452** and transmits that vital sign

33

1   data **454** using the HL7 language (the standard processing language for hospital data and

2   information). The processor at the ICU processes the vital sign data for transmission and storage

3   purposes and transmits that information to the remote location. Vital sign data is then loaded

4   into the data base **458**. The data base for each individual patient is then reviewed and process

5   rules are applied **460** to the vital sign data. These process rules relate to certain alarming

6   conditions which, if a certain threshold is reached, provides an alarm to the intensivist on duty.

7   The vital sign alarm **462** is then displaced to the intensivist who can then take appropriate action.

8   A typical type of rule processing of the vital sign data might be if blood pressure remains at a

9   certain low level for an extended period of time, or if heart rate remains high for an extended

10   period of time. In addition a wide range of other rules are provided which will provide an

11   audible alarm to the intensivist before a critical situation is reached.

12   In addition to the information being provided to the alarming system for the intensivist,

13   the vital sign data **464** is also transmitted **466** into a database warehouse **468** comprising vital

14   sign data **470** from not only the individual patient but from all of the patients being cared for in

15   the ICU. This database warehouse provides the ability to do data mining for trends that can give

16   rise to additional process rules and vital sign thresholding. In addition to the transmission of

17   vital sign data **454** to the remote site, the vital sign data is displayed in real time at the ICU **472**.

18   Referring to **Figure 13A(a)** the diagnostic imaging interaction is illustrated. X-rays for

19   example, are created and transmitted to the command center **472**. Additionally, the information

20   could be ACT scan, MRI, or any other method of medical diagnostic imaging. The x-ray image

21   is captured at the command center **474** where it is stored and in addition displayed on the image

22   monitor **476** for the intensivist to review.

1   Referring to **Figure 13B(b)** the interactive video session is illustrated. A video

2   conferencing session is established **478** regarding a particular patient in an ICU bed. Using the

3   video cameras in each room and/or at the nurses station at the ICU, the patient and/or the nurse

4   can be viewed **480**. On the other end of the video conferencing session is the intensivist who can

5   then both visually and orally communicate with the patient and/or nurse **482**.

6   Referring to **Figure 14** the physician resources and order writing data interface is

7   illustrated. The user interface **484** allows the physicians to access physician resources **486**.

8   These resources provide guideline for the treatment of the critically ill. In this example the

9   intensivist is requested to enter the antibiotic associated with colitis **488**. The system then

10   generates a request for a fecal leukocyte test **490**. This request is translated into an order writing

11   module **496** which results in the actual order for the test **502**. Since the order needs to be

12   transmitted to the appropriate organization for execution, an appropriate order is generated to the

13   microbiology laboratory **500** in this instance. The order results are then achieved **506** and the

14   completion of the order is reported to the order writing assignment manager **496**. In addition, the

15   order writing module **502** also results in a task list **504** of orders for various other individuals in

16   laboratories. In addition, user interface **484** allows the physician to re-enter the physician

17   resources module at any particular location with results of the tests. These tests are then fed into

18   the system to continue with the diagnostic algorithm processing of the patient test results **494**.

19   The user interface also allows interaction with the resident data base **498**   Referring to **Figure**

20   **15** the physician resources database data interface is illustrated. User interface **508** allows the

21   intensivist to interact with the physician resources data base **510**. In this example, resident data

22   base **524** which comprises the identification and background of the resident admitting the patient

23   causes an admission diagnosis **526** to be created. In this example a diagnosis of pancreatitis is

1   illustrated. This diagnosis of pancreatitis 522 alerts the physician resources module 510 which

2   causes an entry for the topic pancreatitis 512. The diagnosis algorithm for pancreatitis 514 is

3   then retrieved and a request for an Apache II score 516 is requested. The system also requests

4   information for operative data 528 describing what if any operations have taken place with

5   respect to this patient, vital sign data 530, request for laboratory information 532, past medical

6   history for the patient 534 and patient demographics 536. All this information is provided to the

7   Apache II score assignment manager 538 which assigns an Apache II score based upon weighted

8   composite up to twenty five different variables. This Apache II score is provided to the Apache

9   II score request module 516. If the severity based Apache II score is greater than or equal to

10   eight the diagnostic of the system continue 520. If the Apache II score is less than eight, the

11   patient is triaged to a none ICU bed 518 since the patient will not necessarily require intensive

12   care thereby saving relatively scarce resources of the ICU for those who are truly critically ill.

13   . Referring to **Figure 16** the automated coding/billing work flow and data flow is

14   illustrated. Clearly ICUs must be paid for the care that they give. At the outset of the visit 540

15   the user interface 542 allows for the input of ICD 9 diagnosis code information concerning

16   complexity of the case, whether the patient is stable, whether the physician involved is the

17   attending physician or consulting physician and all other manner of information required for

18   billing purposes. In addition, resident data 544 is input such as patient demographics, insurance

19   information, physician, guarantor, the date that the service is provided. All this information is

20   provided to the data manager 546 which assembles the required data element for subsequent

21   processing. The data manager sends the demographic, physician, guarantor, insurance and

22   related information to a bill generator 548 which begins to assemble of the information to

23   subsequently generate a bill. Clinical information is provided to the CPT code assignment

1   manager which assigns codes based upon the scores and user input for bill generation purposes.

2   A history of present illness (HPI) score 560 is generated along with a review of systems (ROS)

3   score 562. A PFSH score 564 is generated along with a score relating to the physical exam 566.

4   An MPM score 568 which is a score relating to the severity of the illness is also generated. All

5   of these various scores are provided to the CPT assignment manager 558. Periodically

6   information is downloaded for management reports 556. Once all of the information for the CPT

7   code assignment is generated that information is provided to the bill generator 548 which

8   assembles all the data elements needed to generate an HCFA1500 claim form. The input for the

9   bill generator is then verified 550 where the physician can disagree with code assignments return

10 progress notes and generally review the bill. This smart processing of the HCFA1500 claim

11 form allows for fewer mistakes to be made. If there is any error or additional information that is

12 required, the verification process fails the proposed claim form and information regarding that

13 failure is provided back to the resident data for completion of any missing items. Once an

14 invoice has been verified as having the appropriate information to be submitted the HCFA1500

15 claim form is generated 554. Additional information is written to a billing data file 552 for

16 importation to the patient accounting system of the present invention.

17   Referring to **Figure 17** the order writing data flow is illustrated. Order entry user

18 interface 600 allows the intensivist to order procedures and medication to assist the patients in

19 the ICU. For example, the intensivist can order an ECG 604. Thereafter the order is reviewed

20 and a digital signature relating to the intensivist is supplied 606. Once reviewed and signed off,

21 the order is approved 607 and sent to the data output system 610. Thereafter the data output

22 system prints the order to the printer in the ICU 616. For record keeping purposes the order is

23 exported in the HL7 language to the hospital data system 618. In addition the data output system

1 adds an item to the data base that will subsequently cause an intensivist to check the ECG results.

2 This notification to the task list is provided to the database 614. In addition, as part of the

3 database an orders file relating to the specific patient is also kept. The fact that and ECG has

4 been ordered is entered in the orders file for that patient.

5 In a similar fashion using the order entry user interface 600 the intensivist can order

6 medications 602 for a patient. The medication order then is provided to an order checking

7 system 608. The order checking system retrieves information from the database 614 relating to

8 allergies of the patient and medication list which includes medications which are already being

9 administered to the patient. This allows for the order checking system to check for drug

10 interactions. Further laboratory data is extracted from the database 614 and the order checking

11 system checks to insure that there will be no adverse impact of the recommended dosage upon

12 the renal function of the patient. Once the order checking system 608 is completed, the order is

13 okayed and provided to the order review and signature module 606. In this module the digital

14 signature of the intensivist is affixed to the order electronically and the order is approved 607.

15 Thereafter it is provided to the data output system 610 where again the orders are printed for ICU

16 and 616 and for the hospital data system. In this case, any medications that are ordered are then

17 provided to the medications list file in the database 614 so that the complete list of all

18 medications that are being administered to the ICU patient is current.

19 Referring to **Figure 18** the event log is illustrated. The database 620 contains all manner

20 of notes and data relating to the particular patient that is admitted to the ICU. For example,

21 admission notes 622 are taken upon admission of the patient and stored in the file that is specific

22 to that patient. Progress notes 624 are created during the patients stay within the ICU to note the

23 progress the patient is making giving the various treatments. Procedural notes 626 are also

38

1   created by the intensivist to note what procedures have taken place and what if any events have

2   occurred associated with those procedures. Laboratory data such as positive blood cultures are

3   also stored in the file **628** in the database **620**. Further x-ray data **630** and abnormal CT Scan

4   results are stored in the database.

5   The result of these individual files are then provided to an event log manager **632**. For

6   example, admission notes might contain operations performed. Progress notes **624** might relate

7   to the operations preformed. This information is provided to the event log manager **632**.

8   Admission information is also input to the event log manager as are a listing of the procedures

9   administered to the patient. To the extent there are positive blood cultures in the laboratory data

10   **628** those are provided to the event log manager **632** as are abnormal CT scan results. All of this

11   information is made available through the user interface **634**. Thus the event log presents in a

12   single location key clinical information from throughout a patients stay in the ICU. The event

13   log user interface provides caregivers with a snapshot view of all salient events since admission.

14   All relevant data on procedures and laboratory tests, etc. are presented chronologically.

15   Referring to **Figure 19** the smart alarms of the present invention are illustrated. The

16   smart alarm system constantly monitors physiologic data (collected once per minute from the

17   bedside monitors) and all other clinical information stored in the database (labs, medications,

18   etc). The periodicity of the collection of data is stated for illustrative purposes only. It is well

19   within the scope of the present invention to collect physiological data at more frequent time

20   intervals. Thus, monitor **636** provides information in HL7 form to the interface engine **638**. The

21   physiological data is then formatted by the interface engine for storage in the database **640** where

22   all patient information is maintained. The rules engine **642** searches for patterns of data

23   indicative of clinical deterioration.

1   One family of alarms looks for changes in vital signs over time, using pre-configured

2   thresholds. These thresholds are patient-specific and setting/disease-specific. For example,

3   patients with coronary artery disease can develop myocardial ischemia with relatively minor

4   increases in heart rate. Heart rate thresholds for patients with active ischemia (e.g. those with

5   unstable angina in a coronary care unit) are set to detect an absolute heart rate of 75 beats per

6   minute. In contrast, patients with known coronary artery disease in a surgical ICU have alarms

7   set to detect either an absolute heart rate of 95 beats per minute or a 20% increase in heart rate

8   over the baseline. For this alarm, current heart rate, calculated each minute based on the median

9   value over the preceding 5 minutes, is compared each minute to the baseline value (the median

10   value over the preceding 4 hours). Physiologic alarms can be based on multiple variables. For

11   example, one alarm looks for a simultaneous increase in heart rate of 25% and a decrease in

12   blood pressure of 20%, occurring over a time interval of 2 hours. For this alarm, thresholds were

13   initially selected based on the known association between changes in these two variables and

14   adverse clinical events. Actual patient data were then evaluated to determine the magnitude of

15   change in each variable that yielded the best balance between sensitivity and specificity. This

16   process was used to set the final thresholds for the rules engine.

17   Alarms also track additional clinical data in the patient database. One alarm tracks

18   central venous pressure and urine output, because simultaneous decreases in these two variables

19   can indicate that a patient is developing hypovolemia. Other rules follow laboratory data (e.g.

20   looking for need to exclude active bleeding and possibly to administer blood).

21   The purpose of the rules engine is to facilitate detection of impending problems and to

22   automate problem detection thereby allowing for intervention before a condition reaches a crisis

23   state.

1   Referring to Figure 20 the procedural note-line log is illustrated. This log allows

2   clinicians to evaluate the likelihood that a given procedure might result in further complications.

3   In this example presented in this Figure 20 a catheter removal is illustrated. When a new

4   catheter is inserted in a patient 648 a procedural note is created on the procedure note creation

5   user interface 646. The note is reviewed and a digital signature is attached to the note to

6   associate the note with a particular intensivist 654. The procedure is then approved and is

7   provided to the data output system 656. The procedural note is then printed on the printer in the

8   ICU 658 and is exported in HL7 language to the hospital data system 660. In addition, this also

9   triggers a billing event and the data output system provides appropriate output to the billing

10   module 662 to generate an invoice line item. In addition, the note is stored in the emergency

11   medical record associated with the patient in the database 664. In addition, the line log is

12   updated in the database 664 to show what procedure was administrated to a patient at what time.

13   If there is an existing catheter, that is displayed to the intensivist at the procedure note creation

14   user interface 646. This would show an existing catheter changed over a wire 650. That

15   information is provided to the line id module 652 which extracts information from the line log in

16   the database 664. This information results in a note being created and provided to the note

17   review and signature module 664. Thus the line log contains, for each patient, relevant

18   information about all in-dwelling catheters, including type and location of the catheter, insertion

19   date, the most recent date that the catheter was changed over a wire, and the date the catheter was

20   removed. This information helps clinicians evaluate the likelihood that a given catheter is

21   infected and guides its subsequent management of that procedure.

22   <u>Evidence-based Guidelines, Algorithms, and Practice Standards</u>

41

1 Decision Support Algorithms

2 In order to standardize treatment across ICUs at the highest possible level, decision

3 support algorithms are used in the present invention. These include textural material describing

4 the topic, scientific treatments and possible complications. This information is available in real

5 time to assist in all types of clinical decisions from diagnosis to treatment to triage.

6 All connections among components of the present invention are presently with a high

7 bandwidth T-1 line although this is not meant as a limitation. It is anticipated that other existing

8 and future high bandwidth communication capabilities, both wired and wireless, as well as

9 satellite communications will be suitable for the communications anticipated for the present

10 invention.

11 As noted earlier, a key objective of the present invention is to standardize care and

12 treatment across ICUs. This is effective in the present invention by providing decision support to

13 intensivists as well as information concerning the latest care and practice standards for any given

14 condition. As noted in Table 1 below, a wide variety of conditions is noted. Each of the

15 conditions has an associated guideline of practice standard that can be presented to the intensivist

16 who might be faced with that particular condition in a patient. These guidelines of practice

17 standards can be accessed at the command center/remote location or at the ICU to assist in the

18 treatment of the patient. Thus, the general categories of cardiovascular, endocrinology, general,

19 gastrointestinal, hematology, infectious diseases, neurology, pharmacology, pulmonary, renal,

20 surgery, toxicology, trauma all have guidelines and practice standards associated with them.

21 **Table 1**
22 **EVIDENCE-BASED GUIDELINES**
23 **ALGORITHMS & PRACTICE STANDARDS**
24
25 **DECISION SUPPORT**

CARDIOVASCULAR

BRADYARRHYTHMIAS
CARDIOGENIC SHOCK
CARDIO-PULMONARY RESUSCITATION GUIDELINES
CONGESTIVE HEART FAILURE
EMERGENCY CARDIAC PACING
FLUID RESUSCITATION
HYPERTENSIVE CRISIS
IMPLANTABLE CARDIO-DEFIBRILLATORS
INTRA-AORTIC BALLOON DEVICES
MAGNESIUM ADMINISTRATION IN PATIENTS
MANAGEMENT OF HYPOTENSION, INOTROPES
MYOCARDIAL INFARCTION
MI WITH LEFT BUNDLE BRANCH BLOCK
PA CATHETER GUIDELINES & TROUBLE-SHOOTING
PERMANENT PACEMAKERS & INDICATIONS
PULMONARY EMBOLISM DIAGNOSIS
PULMONARY EMBOLISM TREATMENT
SUPRA-VENTRICULAR TACHYARRHYTHMIAS
UNSTABLE ANGINA
VENOUS THROMBOEMBOLISM PROPHYLAXIS
VENOUS THROMBOSIS: DIAGNOSIS & TREATMENT
VENTRICULAR ARRHYTHMIAS

ENDOCRINOLOGY

ADRENAL INSUFFICIENCY
DIABETIC KETOACIDOSIS
HYPERCALCEMIA: DIAGNOSIS & TREATMENT
HYPERGLYCEMIA: INSULIN TREATMENT
STEROID REPLACEMENT STRATEGIES
THYROID DISEASE

GENERAL

DEALING WITH DIFFICULT PATIENTS AND FAMILIES
END OF LIFE DECISIONS
ETHICAL GUIDELINES

PRESSURE ULCERS
ORGAN PROCUREMENT GUIDELINES

GASTROINTESTINAL

ANTIBIOTIC ASSOCIATED COLITIS
HEPATIC ENCEPHALOPATHY
HEPATIC FAILURE
MANAGEMENT OF PATIENTS WITH ASCITES
NUTRITIONAL MANAGEMENT
ACUTE PANCREATITIS
UPPER GI BLEEDING: STRESS PROPHYLAXIS
UPPER GI BLEEDING: NON-VARICEAL
UPPER GI BLEEDING:VARICEAL

HEMATOLOGY

HEPARIN
HEPARIN-INDUCED THROMBOCYTOPENIA
THE BLEEDING PATIENT
THROMBOCYTOPENIA
THROMBOLYTIC THERAPY
TRANSFUSION GUIDELINES
USE OF HEMATOPOETIC GROWTH FACTORS
WARFARIN

INFECTIOUS DISEASES

ACALCULUS CHOLECYSTITIS
ANTIBIOGRAMS
BLOODSTREAM INFECTIONS
CANDIDURIA
CATHETER RELATED SEPTICEMIA
CATHETER REPLACEMENT STRATEGIES
ENDOCARDITIS PROPHYLAXIS
ENDOCARDITIS DIAGNOSIS AND TREATMENT
FEBRILE NEUTROPENIA
FUO
HIV+ PATIENT INFECTIONS
MENINGITIS
NECROTIZING SOFT TISSUE INFECTIONS

44

NON-INFECTIOUS CAUSES OF FEVER
OPHTHALMIC INFECTIONS
PNEUMONIA, COMMUNITY ACQUIRED
PNEUMONIA, HOSPITAL ACQUIRED
SEPTIC SHOCK
SINUSITIS
SIRS
TRANSPLANT INFECTION PROPHYLAXIS
TRANSPLANT-RELATED INFECTIONS

NEUROLOGY

AGITATION, ANXIETY, DEPRESSION & WITHDRAWAL
BRAIN DEATH
GUILLAIN-BARRE SYNDROME
INTRACEREBRAL HEMORRHAGE
MYASTHENIA GRAVIS
NEUROMUSCULAR COMPLICATIONS OF CRITICAL ILLNESS
NON-TRAUMATIC COMA
SEDATION
STATUS EPILEPTICUS
STROKE
SUB-ARACHNOID HEMORRHAGE

PHARMACOLOGY

AMINOGLYCOSIDE DOSING AND THERAPEUTIC MONITORING
AMPHOTERICIN-B TREATMENT GUIDELINES
ANALGESIA
ANTIBIOTIC CLASSIFICATION & COSTS
DRUG CHANGES WITH RENAL DYSFUNCTION
PENICILLIN ALLERGY
 NEUROMUSCULAR BLOCKERS
VANCOMYCIN
THERAPEUTIC DRUG MONITORING

PULMONARY

ARDS: HEMODYNAMIC MANAGEMENT
ARDS: STEROID USE
ARDS: VENTILATOR STRATEGIES
ASTHMA

BRONCHODILATOR USE IN VENTILATOR PATIENTS
BRONCHOSCOPY & THORACENTESIS GUIDELINES
COPD EXACERBATION & TREATMENT
CXR (INDICATIONS)
NONINVASIVE MODES OF VENTILATION
ENDOTRACHEAL TUBES & TRACHEOTOMY
TREATMENT OF AIRWAY OBSTRUCTION
VENTILATOR WEANING PROTOCOL

RENAL

ACUTE RENAL FAILURE :DIAGNOSIS
ACUTE RENAL FAILURE :MANAGEMENT & TREATMENT
DIALYSIS
DIURETIC USE
HYPERKALEMIA: ETIOLOGY & TREATMENT
HYPERNATREMIA: ETIOLOGY & TREATMENT
HYPOKALEMIA: ETIOLOGY & TREATMENT
HYPONATREMIA: ETIOLOGY & TREATMENT
OLIGURIA

SURGERY

OBSTETRICAL COMPLICATIONS
DISSECTING AORTIC ANEURYSM
POST-OPERATIVE HYPERTENSION
POST-OPERATIVE MYOCARDIAL ISCHEMIA (NON-CARDIAC
ARRHYTHMIAS AFTER CARDIAC SURGERY
POST-OPERATIVE BLEEDING
POST-OPERATIVE MANAGEMENT OF ABDOMINAL
POST-OPERATIVE MANAGEMENT OF OPEN HEART
POST-OPERATIVE MANAGEMENT OF THORACOTOMY
POST-OPERATIVE POWER WEANING
POST-OPERATIVE MANAGEMENT OF CAROTID
WOUND HEALING STRATEGIES

TOXICOLOGY

ACETAMINOPHEN OVERDOSE
ANAPHYLAXIS
COCAINE TOXICITY
ALCOHOL WITHDRAWAL

HYPERTHERMIA
LATEX ALLERGY
UNKNOWN POISONING

TRAUMA

ABDOMINAL COMPARTMENT SYNDROME
BLUNT ABDOMINAL INJURY
BLUNT AORTIC INJURY
BLUNT CARDIAC INJURY
DVT PROPHYLAXIS
EXTREMITY COMPARTMENT SYNDROME
HEAD INJURY
HYPOTHERMIA
IDENTIFICATION OF CERVICAL CORD INJURY
 SPINAL CORD INJURY
OPEN FRACTURES
PENETRATING ABDOMINAL INJURY
PENETRATING CHEST INJURY

1

2   Referring to **Figures 21A-B**, the acalculous cholecystitis decision support algorithm of

3   the present invention is illustrated. If an intensivist suspects that acalculous cholecystitis may be

4   present, the intensivist may not be certain of all of the aspects that would be indicative of this

5   particular condition. Therefore, the intensivist is lead through a decision support algorithm,

6   which first causes the intensivist to determine if the patient is clinically infected, either febrile or

7   leukocystosis **800**. If this criteria is not met, the intensivist is prompted that it is unlikely that the

8   patient has acalculous cholecystitis **802**.

9   If the patient is clinically infected **800**, the intensivist is prompted to determine whether

10   the patient has had a previous cholesystectomy **804**. If patient has had a previous

11   cholesystectomy, the intensivist is prompted that it is very unlikely that the patient has

12   acalculous cholecystitis **806**. Alternatively, if a patient has not had a previous cholesystectomy,

13   the intensivist is prompted to determine whether the patient has any of seven (7) risk factors,

1   specifically: 1) Prolonged intensive care unit (ICU) stay (defined as greater than six (6) days); 2)

2   recent surgery (particularly aortic cross clamp procedures); 3) hypotension; 4) positive end-

3   expiratory pressure (PEEP) greater than ten (10) centimeters (cm); 5) transfusion greater than six

4   (6) units of blood; 6) inability to use the gastrointestinal (GI) tract for nutrition; or 7)

5   immunosuppresssion (AIDS, transplantation, or leukemia) 808. If the patient has none of these

6   seven risk factors, the intensivist is prompted that the patient probably does not have acalculous

7   cholecystitis 810.

8   If the patient has any of the seven risk factors 808, the intensivist is prompted to

9   determine whether the patient has any of the following symptoms: right upper quadrant (RUQ)

10   tenderness; elevated alkalinephosphatase; elevated bilirubin; or elevated livert transaminases

11   812. If the patient has none of these four (4) symptoms 812, the intensivist is prompted to

12   consider other more likely sources of infection (see fever of unknown origin or FUO) 814. If the

13   infection remains undiagnosed following an alternative work-up, the intensivist is prompted to

14   re-enter the algorithm 814.

15   If the patient has any of these four (4) symptoms 812, the intensivist is prompted to

16   determine whether alternative intra-abdominal infectious sources are more likely 816. If

17   alternative intra-abdominal infectious sources are not more likely, the intensivist is prompted to

18   determine whether the patient is sufficiently stable to go for a test 826. If the patient is

19   sufficiently stable to go for a test, the intensivist is prompted to perform an mso4

20   Cholescintigraphy 836. The normal AC is excluded 838. If the test indicates an abnormality, the

21   intensivist is prompted to consider a cholecystectomy or precutaneous drainage 840. If the

22   patient is not sufficiently stable to go for a test, the intensivist is prompted to perform a bedside

23   ultrasound 828. If no other infectious etiologies are identified and no abnormalities of the gall-

24   bladder are noted but: a) the patient remains ill 830, the intensivist is prompted to consider

25   empiric cholecystostomy 832. If no other infectious etiologies are identified and no

26   abnormalities of the gall bladder are noted but: b) the patient is improving 830, the intensivist is

1   prompted to continue to observe the patient **834**.

2   If alternative intra-abdominal infectious sources are more likely **816**, the intensivist is

3   prompted to determine whether the patient is sufficiently stable to go for a test **818**. If the patient

4   is sufficiently stable to go for a test **818**, the intensivist is prompted to perform an abdominal CT

5   scan **820**. If no other infectious etiologies are apparent and the test: a) demonstrates

6   abnormalities of the gall-bladder but not diagnostic; or b) no gall-bladder abnormalities are noted

7   **822**, the intensivist is prompted to maintain continued observation of the patient **824**.

8   Alternatively, if this criteria not met **822**, the intensivist is prompted to perform an mso4

9   cholescintigraphy **836**. Normal AC is excluded **838**. If the test is abnormal, the intensivist is

10 prompted to consider cholecystectomy or precutaneous drainage **840**. If the patient is not

11 sufficiently stable to go for a test, the intensivist is prompted to perform a bedside ultrasound

12 **828**. If no other infectious etiologies are identified and no abnormalities of the gall-bladder are

13 noted but: a) the patient remains ill **830**, the intensivist is prompted to consider empiric

14 cholecystostomy **832**. If no other infectious etiologies are identified and no abnormalities of the

15 gall bladder are noted but: b) the patient is improving **830**, the intensivist is prompted to continue

16 to observe the patient **834**.

17 Referring to **Figure 22**, the adrenal insufficiency decision support algorithm of the

18 present invention is illustrated. When an intensivist suspects an adrenal problem may be

19 presented in a patient, the intensivist may initiate the adrenal insufficiency decision support

20 algorithm which prompts questions concerning all aspects of the condition. First the intensivist

21 is prompted to determine whether the patient is either hypotensive and/or has been administered

22 pressors for forty-eight hours or longer **900**. If neither condition is met, the system advises the

23 intensivist that it is unlikely that an adrenal problem is present **902**.

24 If one or both conditions are met, the intensivist is asked whether an obvious cause for

25 hypotensive blood pressure or treatment with pressors are manifested, such as hypovolemia or

26 low blood volume, myocardial dysfunction, or spinal injury **904**. If at least one of these obvious

1 causes is present, the intensivist is alerted by the system that the underlying cause must first be

2 treated **906.** If treatment of a suspected underlying cause is reversed, yet the hypotension or

3 pressor need persists, the intensivist is further directed to determine whether other adrenal

4 problems have occurred in the patient's history **908, 910, 912**

5   In order to examine prior treatment issues, the intensivist is first prompted by the system

6 to determine if the patient has been treated with steroids in the previous six months for at least a

7 two week period **908.** Next, the intensivist is prompted to determine whether the patient has

8 hyponatremia or hyperkalemia **910.** The intensivist is also prompted to determine whether the

9 patient has experienced anticoagulation or become coagulopathic prior to the hypotension or

10 pressor treatment **912.** According to the responses provided by the intensivist to the system

11 queries or blocks **908, 910,** and **912,** the system calculates a treatment action **914** as follows: The

12 array of possible responses to diagnosis questions **908, 910,** and **912** are given a Decision Code

13 as shown in Table 1: Adrenal Insufficiency Considerations, below.

14

15 Table 1: Adrenal Insufficiency Considerations

Question 1 908	Question 2 910	Question 3 912	Decision Code
N	N	N	A
N	N	Y	A
N	Y	N	B
N	Y	Y	C
Y	Y	Y	C
Y	N	N	D
Y	Y	N	B
Y	N	Y	D

Y	Y	Y	C

1

2 The possible decision codes of Table 1 are as follows:

Decision Code	Treatment Action
A	Do cosyntropin stim test
B	Consider possible Adrenal Insufficiency. Give decadron 5 mg IV, so cosyntropin stim test and empirically treat with hydrocortione 50 mg IV every 8 hours until stim test results return.
C	Consider possible Adrenal Insufficiency, secondary to adrenal hemorrhage. Give decadron 5 mg IV, so cosyntropin stim test and empirically treat with hydrocortione 50 mg IV every 8 hours until stim test results return.
D	Do cosyntropin stim test, may empirically treat with hydrocortisone 25-50 mg IV every 8 hours until stim test results return

3

4 Besides specialized treatment actions listed in the decision codes above, the intensivist is

5 directed to administer a cosyntropin stimulation test **914** in order to see how much cortisone the

6 adrenal gland is producing.

7 After performing the cosyntropin stimulation test, the intensivist is prompted to enter the

8 patient's level of cortisol before administering cosyntropin and thirty minutes afterwards **916**.

9 The software analyzes the test results as follows:

10 The results in Table 2, shown below, are shown as having certain decision codes A through F.

11 **Table 2: Cosyntropin Stimulation Test Results**

basal (A) ≤ 15	basal (B) 15-20	basal (C) > 25
stim (D) < 5	stim (E) 5-10	stim (F) > 10

12

13 Depending upon the outcome of the analysis of Table 2, one of the treatment actions, shown

1   below in Table 3, will be displayed **918**.

2   **Table 3: Cosyntropin Test Result Treatment Actions**

Decision Code	Treatment Action
A + D	<u>Adrenal insufficiency diagnosed - treat with hydrocortisone 50 mg IV every 8 hours and consider endocrine consult</u>
A + E B + D	Probable Adrenal insufficiency- treat with hydrocortisone 25-50 mg IV every 8 hours and taper as intercurrent illness improves
A + F B + E	Possible Adrenal insufficiency- consider treatment with hydrocortisone 25 mg IV every 8 hours and taper as intercurrent illness improves
A + F B + F C + E C + F	Adrenal insufficiency unlikely- would not treat

3

4   Referring to **Figure 23**, the blunt cardiac injury decision support algorithm of the present

5   invention is illustrated. If an intensivist suspects that blunt cardiac injury may be present, the

6   intensivist may not be certain of all aspects that would be critical to or indicative of this

7   particular condition. Therefore, the intensivist is lead through a decision support algorithm,

8   which first causes the intensivist to determine whether any of seven (7) risk factors are present:

9   1) was thoracic impact greater than fifteen (15) mph; 2) was the steering wheel deformed; 3) was

10   there precordial ecchymosis, contusions, or abrasions; 4) was marked precordial tenderness

11   present; 5) was there a fractured sternum; 6) were bilateral rib/costal cartilage fractures present;

12   7) were thoracic spine fractures present **1000**. If none of the 7 risk factors are present, the

13   intensivist is prompted that no further evaluation is necessary **1002**. If any of the 7 risk factors

14   are present, the intensivist is prompted to obtain an electrocardiogram (ECG) and chest X-ray

15   (CXR) **1004**.

16   Once the results of the ECG and CXR are obtained, the intensivist is prompted to

52

1   determine: whether the ECG results are abnormal, with abnormal being defined as anything

2   other than sinus rhythm, including ectopy and unexplained sinus tachycardia (greater than 100

3   beats/minute); and whether the CXR results are abnormal, with abnormal being defined as any

4   skeletal or pulmonary injury, especially cardiac enlargement **1006**. If either the ECG or CXR are

5   not abnormal, the intensivist is prompted that a monitored bed is unnecessary for the patient

6   **1008**. If either the ECG or CXR are abnormal, the intensivist is prompted to determine whether

7   there is any hemodynamic instability (hemodynamic instability being defined as the absence of

8   hypovolemia, spinal cord injury, or sepsis) that cannot be explained by hypovolemia, spinal cord

9   injury, or sepsis **1010**.

10   If this criteria is not met, the intensivist is prompted: that the patient should be in a

11   monitored bed; that the ECG should be repeated at 24 hours; that, at any time, if unexplained

12   hemodynamic instability is present, the intensivist should request a stat echo; and that, if blunt

13   thoracic aortic injury is also suspected, a transesophogeal echocardiogram (TEE) is favored over

14   a transthoracic echocardiogram (TTE) **1012**. Once the results of these tests are obtained, the

15   intensivist is prompted further to determine whether ectopy, arrhythmia, or abnormality is

16   present on the ECG **1014**. If none of these criteria are met, the intensivist is prompted that

17   cardiac injury is excluded **1016**. If any of these criteria are met, the intensivist is prompted that

18   he should consider monitoring the patient for an additional 24 hours **1018**.

19   If the internist determines that there is any hemodynamic instability that cannot be

20   explained by hypovolemia, spinal cord injury, or sepsis **1010**, he is prompted: to perform a stat

21   echo; and, if blunt thoracic aortic injury is also suspected, that a transesophogeal echocardiogram

22   (TEE) is favored over a transthoracic echocardiogram (TTE) **1020**. Once the results of the stat

23   echo are obtained, the intensivist is prompted to determine whether the echo is abnormal with

1   possible causes for the abnormality being: pericardial effusion (tamponade; hypokineses or

2   akinesis (wall motion); dilatation or reduced systolic function; acute valvular dysfunction; and/or

3   chamber rupture **1022**. If the stat echo is abnormal, the intensivist is prompted to treat as

4   indicated for the particular cause of the abnormality **1026**. If the stat echo is not abnormal, the

5   intensivist is prompted to continue to monitor the patient and repeat the ECG at 24 hours **1024**.

6   Once the results of the ECG are obtained, the intensivist is prompted to determine

7   whether ectopy, arrhythmia, or abnormality are present on the ECG **1014**. If this criteria is not

8   met, the intensivist is prompted that cardiac injury is excluded **1016**. If this criteria is met, the

9   intensivist is prompted that he should consider monitoring the patient for an additional 24 hours

10 **1018**.

11   Referring to **Figures 24A-B**, the candiduria decision support algorithm, which is yet

12 another decision support algorithm of the present invention is illustrated. In the candiduria

13 decision support algorithm, the intensivist is presented with the criteria for diagnosing

14 candiduria, or severe fungal infection. First, the intensivist determines whether the patient has

15 any medical conditions that render the patient prone to fungal infections, such as diabetes, GU

16 anatomic abnormality, renal transplant, or pyuria **1100**. If there are no such conditions, the

17 intensivist is next prompted by the system to look for dissemination or spreading of the fungal

18 infection **1102**. If the infection does not seem to have spread, the intensivist is prompted to

19 change the patient's catheter and test for pyuria after twenty four hours have passed **1104**.

20   The intensivist is prompted by the system to determine whether the patient can have P.O.

21 **1106**. If the patient can take P.O., the system next prompts the intensivist to determine whether

22 azoles, an organic compound for inhibiting fungal growth, have been administered in the past

23 three days to fight the infection **1108**. If azoles have been previously administered, the systemic

1   infection diagnosis is confirmed and the intensivist is referred to the systemic amphotericin

2   dosing algorithm **1110**. If azoles have not been previously administered, directions for the

3   proper treatment dosage of fluconazole (a type of azole) is provided to the intensivist along with

4   adjustments for the species of fungus found **1112**. Where the patient cannot take P.O., the

5   intensivist is again referred to the systemic amphotericin dosing algorithm **1114**.

6   When the patient does have some condition prone to fungal infection, the intensivist is

7   prompted to determine what other signs of dissemination are exhibited in the patient **1116**. The

8   intensivist is prompted to see if the patient can take P.O. If the patient cannot take P.O., the

9   intensivist is referred to the systemic amphotericin dosing algorithm **1120**. If the patient can take

10   P.O., the intensivist is prompted to check whether azoles have been administered in the previous

11   three days **1122**. If azoles have been administered, the systemic infection is confirmed and the

12   intensivist is referred to the systemic amphotericin dosing algorithm **1124**. If no azoles have

13   been administered previously, the intensivist is given instructions for administering fluconazole

14   to treat the fungal infection **1126**.

15   If there is no evidence of dissemination, the intensivist is still prompted to determine

16   whether the patient can take P.O. **1128**. Where the patient cannot take P.O., directions are

17   provided to administer amphotericin bladder washing procedures **1130**. If the patient cannot take

18   P.O., the intensivist is prompted to determine whether azoles have been administered in the

19   previous three days **1132**. If azoles have been administered, the systemic infection is confirmed

20   and the intensivist is referred to the systemic amphotericin dosing algorithm **1134**. If no azoles

21   have been administered previously, the intensivist is given instructions for administering

22   fluconazole to treat the fungal infection **1136**.

23

1   Referring to **Figures 25A-B**, the Cervical Spine Injury decision support algorithm of the

2   present invention is illustrated. If an intensivist suspects that a cervical spine injury may be

3   present, the intensivist may not be certain of all of the factors that would be indicative of this

4   particular condition. Therefore, the intensivist is lead through a decision support algorithm,

5   which first prompts the intensivist to determine if the patient is awake, alert, not intoxicated, and

6   has no mental status changes **1200**. If this criteria is met, the intensivist is prompted to

7   determine whether the patient has any neck pain **1202**. If the patient does not have any neck

8   pain, the intensivist is prompted to determine whether the patient has any other pain which would

9   distract from their neck pain **1204**. If this criteria is not met, the intensivist is prompted to

10   determine whether the patient has any neurologic deficits **1206**. If this criteria is not met, the

11   intensivist is prompted that a stable C-spine is present if the patient can flex, extend, move neck

12   left/right without pain and without neck tenderness to palpitation **1208**. The intensivist is

13   prompted further that he can remove the collar **1208**.

14   Alternatively, if the patient does have neck pain **1202**, the intensivist is prompted to order

15   3 x rays **1210** consisting of: 1) lateral view revealing the base of the occiput to the upper border

16   of the first thoracic vertebra; 2) anteroposterior view revealing spinous processes of the second

17   cervical through the first thoracic vertebra; and 3) an open mouth odontoid view revealing the

18   lateral masses of the first cervical vertebra and entire odontoid process **1210**. If the x rays are

19   normal the intensivist is prompted to consider extension then flexion lateral x rays; if normal he

20   is prompted that he can remove the collar; if abnormal, he is prompted to obtain a surgical

21   consult **1212**. If the x rays are abnormal, the intensivist is prompted to obtain a surgical consult

22   and order a CT scan **1214**. If the x rays are indeterminate, the intensivist is prompted to order a

23   CT scan **1216**.

56

1   Alternatively, if the patient has no other pain which would distract from their neck pain

2   1204, the intensivist is prompted to order 3 x rays (the same types of x rays described in 1210

3   above with the same prompting based on normal, abnormal, or indeterminate x rays) 1218.

4   If the patient does have neurologic deficits 1206, the intensivist is prompted to determine

5   whether the neurologic deficit is referable to the cervical spine 1226. If this criteria is not met,

6   the intensivist is prompted to order 3 x rays (the same types of x rays described in 1210 above

7   with the same prompting based on normal, abnormal, or indeterminate x rays) 1218. If the

8   neurologic deficit is referable to the cervical spine 1226, the intensivist is prompted that the

9   patient should obtain immediate spine trauma surgery consult and CT or MRI (if available) 1228.

10   Alternatively, if the intensivist determines that the patient does not pass the criteria of

11   being awake, alert, not intoxicated and having no mental status changes 1200, the intensivist is

12   prompted to determine whether the patient has severe head trauma 1232. If this criteria is met,

13   the intensivist is prompted to order CT of the neck with head CT 1236. If this criteria is not met,

14   the intensivist is prompted to determine whether the patient has any neurologic deficit referable

15   to the cervical spine 1234. If the intensivist determines that the patient does have a neurologic

16   deficit referable to the cervical spine, the intensivist is prompted that the patient should obtain

17   immediate spine trauma surgery consult and CT or MRI (if available) 1228. If the intensivist

18   determines that the patient does not have a neurologic deficit referable to the cervical spine 1234,

19   he is prompted to order 3 x rays (the same types of x rays described in 1210 above with the same

20   prompting based on normal, abnormal, or indeterminate x rays) 1218.

21   Referring to Figures 26A-B, the Oliguria decision support algorithm of the present

22   invention is illustrated. If an intensivist suspects that Oliguria may be present, the intensivist

23   may not be certain of all of the aspects that would be indicative of this particular condition.

1   Therefore, the intensivist is lead through a decision support algorithm, which first causes the

2   intensivist to determine if the patient is oliguric, with the criteria being passage of less than 25 cc

3   of urine in a period of 2 hours 1300. If this criteria is met the intensivist is prompted to

4   determine whether the patient is anuric (the criteria for which is passage of less than 10 cc of

5   urine in a 2 hour period) in spite of fluid administration 1302.

6   If this criteria is met, the intensivist is prompted to determine whether the urinary catheter

7   is working by flushing the catheter 1304. The intensivist is then prompted to determine whether

8   the catheter is functioning 1306. If the catheter is not functioning, the intensivist is prompted to

9   replace or reposition the catheter 1308. If the catheter is functioning, the intensivist is prompted

10   to determine whether the patient has a history of: 1) renal stone disease; 2) abdominal, pelvic, or

11   retroperitoneal cancer; or 3) recent pelvic or retroperitoneal surgery 1310. If any of these criteria

12   are met, the intensivist is prompted to perform the following actions: 1) do renal ultrasound

13   emergently to rule out obstruction; 2) while waiting for ultrasound, administer fluid at the rate of

14   7-15 ml/kg of bodyweight; and 3) send urine for specific gravity determination 1312. Based on

15   the renal ultrasound test results, the intensivist is prompted to determine whether an obstruction

16   is present 1314. If an obstruction is determined to be present, the intensivist is prompted to

17   consult a urologist immediately 1316.

18   Alternatively, if the intensivist determines that the patient does not have a history of: 1)

19   renal stone disease; 2) abdominal, pelvic, or retroperitoneal cancer; or 3) recent pelvic or

20   retroperitoneal surgery 1310, the intensivist is prompted to determine whether: 1) the patient has

21   a history of heart failure or known ejection fraction of less than 30 percent; or 2) there are rales

22   on the physical exam 1318.

1   Alternatively, if following the renal ultrasound test, the intensivist determines that there is

2   no obstruction the intensivist is prompted to determine whether: 1) the patient has a history of

3   heart failure or known ejection fraction of less than 30 percent; or 2) there are rales on the

4   physical exam **1318**.

5   If the intensivist determines that the patient is not anuric **1302**, then the intensivist is

6   prompted to determine whether: 1) the patient has a history of heart failure or known ejection

7   fraction of less than 30 percent; or 2) whether there are rales on the physical examination **1318**.

8   If this criteria is not met, the intensivist is prompted to administer fluids to the patient at the rate

9   of 10-20 ml/kg of bodyweight **1320** and send the patient's urine sample for a specific gravity test

10   **1322** as more fully described in **Figures 26B-CA**.

11   Alternatively, if the patient does: 1) have a history of heart failure or known ejection

12   fraction less than 30 percent; or 2) there are rales on the physical exam **1318**, the intensivist is

13   prompted to determine whether there has been a chest x-ray (CXR) in the last 6 hours **1324**. If

14   this criteria is not met, the intensivist is prompted to determine whether there has been a change

15   in respiratory status **1326**. If there has been no change in the respiratory status, the intensivist is

16   prompted to administer 7-15 ml of fluids per kg of bodyweight **1328** and to send the patient's

17   urine sample for a specific gravity test.

18   Alternatively, if the intensivist determines that there has been a change in respiratory

19   status **1326**, the intensivist is prompted to: 1) do a chest x-ray; and 2) determine whether there is

20   evidence of edema or congestion **1334**. If there is evidence of edema or congestion **1334**, the

21   intensivist is prompted to: 1) insert a PA catheter to measure wedge pressure and liver function

22   to direct fluid replacement; and 2) send urine creatinine and sodium **1332**.

1   If the intensivist determines that there has been a CXR in the last 6 hours **1324**, the

2   intensivist is prompted to determine whether there is evidence of edema or congestion **1330**. If

3   there is no evidence of edema or congestion, the intensivist is prompted to administer 7-15 ml of

4   fluids per kg of bodyweight **1328** and send the patient's urine for a specific gravity test **1322**.

5   Alternatively, if the intensivist determines there is evidence of edema or congestion **1330**,

6   the intensivist is prompted to: : 1) insert a PA catheter to measure wedge pressure and liver

7   function to direct fluid replacement; and 2) send urine creatinine and sodium **1332**.

8   Referring now to **Figures 26C-DA**, the oliguria algorithm description continues.

9   Following the specific gravity test of the patient's urine, the intensivist is prompted to determine

10   whether the results indicate the specific gravity is less than 1.018. If this criteria is met, the

11   intensivist is prompted to: 1) send blood and urine immediately to test for blood urea nitrogen

12   (BUN), creatinine, electrolytes, and Hgb, and spot urine for creatinine, sodium, and sediment;

13   and 2) administer 5-10 ml of fluid per kg of bodyweight **1356**. Once the results of these tests are

14   obtained, the intensivist is prompted to determine what is the Hgb **1338**.

15   If the Hgb has increased by more than 1.5 gm/dl compared to the previous hgb **1340**, the

16   intensivist is prompted to: 1) administer fluids 5-10 ml/kg of bodyweight and follow the urine

17   output closely **1342**. Following this, the intensivist is prompted to determine whether the labs

18   confirm renal failure by use of the formula FE_{Na}=Urine Na x Serum Creatinine/Urine Creatinine

19   x Serum Na x 100 **1344**.

20   If the Hgb is within 1.5 gm/dl from the previous hgb or no comparison **1352**, the

21   intensivist is prompted to determine what is the mean blood pressure **1354**. If the mean blood

22   pressure is determined to be within 20 percent or higher than the baseline blood pressure **1356**,

23   the intensivist is prompted to determine whether the labs confirm renal failure **1344**. If the mean

1   blood pressure is determined to be greater than 20 percent below the baseline pressure **1358**, the

2   intensivist is prompted to give additional fluids and consider invasive hemodynamic monitoring

3   **1360**. Following this, the intensivist is prompted to determine whether the labs confirm renal

4   failure by use of the formula FE_{Na}=Urine Na x Serum Creatinine/Urine Creatinine x Serum Na x

5   100 **1344**.

6   Alternatively if the Hgb has decreased by 1.5 gm/dl compared to the previous hgb **1362**,

7   the intensivist is prompted to: 1) transfuse PRBCs as needed; 2) look for source of bleeding and

8   check PT, aPTT, & platelet count **1364**. Following this, the intensivist is prompted to determine

9   what is the mean blood pressue **1354**. If the mean blood pressure is determined to be greater

10   than 20 percent below the baseline pressure **1358**, the intensivist is prompted to give additional

11   fluids and consider invasive hemodynamic monitoring **1360**. Following this, the intensivist is

12   prompted to determine whether the labs confirm renal failure by use of the formula FE_{Na}=Urine

13   Na x Serum Creatinine/Urine Creatinine x Serum Na x 100 **1344**.

14   If the labs do not confirm renal failure, as indicated by $FE_{Na} \leq 1$ percent **1346**, the

15   intensivist is prompted to: 1) continue to administer fluids and follow urine output; and 2)

16   recheck creatinine in 6-12 hours **1348**.

17   Alternatively, if the labs do confirm renal failure, as indicated by $FE_{Na} \rangle 1$ percent **1350**,

18   the intensivist is prompted to: 1) place central venous pressure (CVP); 2) Assure adequate

19   intravascular volume; 3) give trial of diuretics: 40 mg lasix IV, if no response in 1 hour, give

20   hydrodiuril 500 mg IV, wait 20-30 minutes then give 100 mg lasix, if persistent oliguria, restrict:

21   1) fluids; 2) potassium & phosphate; if diuresis ensues, restrict only potassium & phosphate; in

22   both situations, adjust all renally excreted medications; and 4) see acute renal failure **1350**.

1   Referring now to **Figure 26E_B**, the oliguria algorithm description continues.

2   Alternatively, following the specific gravity test of the patient's urine, the intensivist is prompted

3   to determine whether the results indicate the specific gravity is greater than or equal to 1.018

4   **1336**. If this criteria is not met **1364**, the intensivist is prompted to determine whether the urine

5   is dark or tea colored **1366**. If this criteria is met, the intensivist is prompted to: 1) check

6   creatinine phospho/kinase; and 2) force fluids to induce diuresis **1368**.

7   If the intensivist determines that the urine is not dark or tea colored, the intensivist is

8   prompted to: 1) administer 10-20 ml of fluids per kg of bodyweight; and 2) check hgb **1370**. The

9   intensivist is then prompted to determine what is the hgb **1372**.

10   If the hgb is determined to be greater than 1.5 gm/dl higher than the previous hgb **1374**,

11   the intensivist is directed to: 1) force fluids; and 2) continue to follow the urine output **1376**.

12   Alternatively, if the hgb is determined to be within 1.5 gm/dl of the last hgb or there is no

13   hgb for comparison **1378**, the intensivist is prompted to determine what is the mean blood

14   pressure **1380**. If the mean blood pressure is determined to be 20 percent or higher than the

15   baseline pressure **1382**, the intensivist is prompted to: 1) continue to administer fluids; 2) follow

16   urine output; and 3) check creatinine in 6-12 hours **1384**. If the mean blood pressure is

17   determined to be greater than 20 percent below the baseline pressure **1386**, the intensivist is

18   prompted to: 1) continue to push fluids; 2) consider invasive hemodynamic monitoring; and 3) if

19   post-op abdominal trauma, consider abdominal compartment syndrome **1388**.

20   If the hgb is determined to be greater than 1.5 gm/dl below the previous hgb **1390**, the

21   intensivist is prompted to: 1) transfuse blood as needed; 2) look for bleeding source; 3) check

22   PT, aPPT & platelet count; 4) continue to push fluids; and 5) recheck hgb in 1-2 hours **1392**.

23   Referring to **Figures 27A-B**, the open fractures decision support algorithm of the present

1 invention is illustrated. Open fractures are where bone, cartilage, or a tooth break and push

2 through the skin surface. The intensivist is first prompted by the system to determine whether

3 the patient has an open fracture **1500**. If one has occurred, the intensivist must then determine

4 whether the wound is contaminated with soil, or was inflicted in a barnyard **1502** in order to

5 address higher risk of infection. If the wound is contaminated with soil, or was inflicted in a

6 barnyard, the intensivist is prompted to administer a high dose of penicillin to the antibiotics

7 prescribed **1504**. The intensivist is also prompted to take several treatment steps **1506**. These

8 treatment steps include administering tetanus prophylaxis, such an antitoxin injection,

9 monitoring staphylococcus aureus until twenty-four hours after surgery, caring for the wound

10 within six hours, and where the injury is found to be more severe during surgery, the intensivist

11 is prompted to administer aminoglycosides for seventy two hours.

12 　　　If the wound is not contaminated with soil, or was inflicted in a barnyard, the intensivist

13 is next prompted to determine the severity of the wound **1508**. To do so, the intensivist must

14 determine the length of the wound and corresponding soft tissue damage. If the wound is either

15 less than one centimeter and clean or greater than a centimeter long without extensive soft tissue

16 damage, the Intensivist is prompted to take several treatment steps **1506** as previously described.

17 Where the soft tissue damage is extensive or amputation has occurred, the intensivist is

18 prompted by the system to make further determinations **1510, 1512, 1514** about the wound

19 caused by the fracture. The intensivist is prompted to determine if enough soft tissue coverage is

20 remaining for the wound to close and heal **1510**, if any arterial repair is needed **1512**, and if

21 extensive soft tissue damage with periostitial injury, and bone exposure **1514**. If there is

22 adequate soft tissue coverage, the intensivist is advised that risk of infection is low and directed

23 to take treatment actions **1516**. If arterial damage requiring repair is present, the intensivist is

1   advised by the system that risk of infection is moderate to high and given treatment instructions

2   1518. Where there is soft tissue injury with periostitial stripping and bone exposure, the

3   intensivist is alerted by the system that risk of infection is high and given treatment instructions

4   1520. The treatment instructions in each case 1516, 1518, 1520 include administering tetanus

5   prophylaxis, such an antitoxin injection, caring for the wound within six hours, and performing:

6   monitoring for staphylococcus aureus, and administering aminoglycosides and high doses of

7   penicillin, all for seventy two hours before and after any operative procedures.

8   If the intensivist has determined that no exposed fracture has occurred, the system next

9   prompts the intensivist to determine whether there is any evidence of neuro-vascular damage

10 1522. If there is evidence of neuro-vascular damage, the intensivist is prompted to consult with a

11 nerosurgeon or vascular surgeon immediately 1524. If the intensivist determines there is no

12 evidence of neuro-vascular damage to the patient, the system next prompts the intensivist to

13 determine whether the patient has compartment syndrome 1526. If there is evidence of

14 compartment syndrome seen in the patient, the intensivist is prompted to consult orthopedics

15 right away 1528. If there is no evidence of compartment syndrome seen in the patient, the

16 intensivist is still prompted to consult orthopedics, but without any prompt for time sensitivity

17 1530.

18   Referring to Figures 28A-B, the Pancreatitis diagnostic algorithm of the present

19 invention is illustrated. To evaluate whether a patient has pancreatitis, the intensivist is first

20 prompted to examine whether severe epigastric abdominal pains and amylase levels three times

21 greater than normal are present in the patient 1600. If neither or one of the conditions is present,

22 the intensivist is prompted to consider other causes of the abdominal pain, such as mesenteric

23 ischemia, a perforated ulcer, intestinal obstruction, biliary colic, or an ectopic pregnancy 1602.

1   If severe epigastric abdominal pains and amylase levels three times greater than normal

2   are present, the intensivist is next prompted to provide the Ranson Criteria which is a criteria

3   associated with the severity of pancreatitis and the potential outcome or prognosis at that

4   particular level of severity, or Apache II score which is also a score associated with the severity

5   of the disease and the potential prognosis at a particular level of the patient **1604**. If the patient

6   has a Ranson Criteria less than three or an Apache II score of less than eight, the intensivist is

7   prompted by the system to consider removing the patient from the Intensive Care Unit **1606**.

8   However, if the patient has a Ranson Criteria greater than three or an Apache II score of greater

9   than eight, the intensivist is instructed to perform an abdominal ultrasound test within twenty-

10   four hours **1607**. If the results of the ultrasound test show a biliary obstruction, the intensivist is

11   instructed to consider performing an ERCP to find and remove any gallstones **1608**.

12   If the abdominal ultrasound results do not show any biliary obstruction, intensivist is next

13   prompted to perform more diagnostic tests **1610**. The intensivist is directed to perform a

14   Dynamic IV contrast and an abdominal Computerized Tomography (CT) scan. If the intensivist

15   does not suspect a surgical condition exists, such as a perforated ulcer, mesenteric infarction or

16   pancreatic infection, the tests may be performed after three days have passed. If the intensivist

17   does suspect a surgical condition exists, the tests should be performed within three days. In

18   either case, if the patient has creatinine levels greater than or equal to 2 miligrams per dl, the

19   intensivist should not perform the Dynamic IV contrast test.

20   Once the CT scan is performed, the intensivist is prompted to determine whether

21   necrotizing pancreatitis is present **1612**. The intensivist is next required to determine whether

22   the patient has improved since admission **1614**. If no improvement has been seen, the intensivist

23   is directed to perform percutaneous fluid aspiration and do a gram stain culture the collected

1   fluid **1616**. If the culture shows infection **1618**, the intensivist is directed to perform surgical

2   debridement of the pancreas **1620**. If the results of the culture are sterile **1622**, the intensivist is

3   directed to closely follow up on the patient's condition **1624** and watch for clinical deterioration

4   **1626**. If the patient does further deteriorate, the intensivist is then instructed to perform a

5   surgical debridement of the pancreas **1628**. If the patient does not deteriorate, the intensivist is

6   still prompted to closely follow the patient's condition **1630**.

7   Where the CT scan does not show signs of necrotizing pancreatitis **1612**, the intensivist is

8   prompted by the system to closely observe the patient **1632**. The intensivist is also prompted to

9   check whether clinical deterioration is occurring **1634**. If no deterioration is observed, the

10   intensivist continues to observe the patient's condition **1636**. If clinical deterioration is occurring

11   **1634**, the intensivist is directed to perform percutaneous fluid aspiration and do a gram stain

12   culture the collected fluid **1616**. If the culture shows infection **1618**, the intensivist is directed to

13   order surgical debridement of the pancreas **1620**. If the results of the culture are sterile **1622**, the

14   intensivist is directed to closely follow up on the patient's condition **1624** and watch for clinical

15   deterioration **1626**. If the patient does further deteriorate, the intensivist is then prompted to

16   order a surgical debridement of the pancreas **1628**. If the patient does not deteriorate, the

17   intensivist is still directed by the system to closely follow the patient's condition **1630**.

18   Referring to **Figures 29A-B**, the penicillin allergy diagnosis algorithm of the present

19   invention is illustrated. In order to diagnose a penicillin allergy, the intensivist is first prompted

20   to determine whether the patient has a history suggestive of previous penicillin or cephalosporin

21   anaphylaxis **1700**. Various known reactions, including angioedema, flushing, pruritis, airway

22   obstruction, syncope, and hypertension, are displayed for the intensivist's review. If the patient

23   has previously had any of these reactions, the intensivist is prompted to determine whether the

1   patient has ever taken synthetic or partially synthetic abtibiotics, such as ampicillin, amoxicillin,

2   duricef or kefzol, without any anaphylaxis symptoms 1702. If the patient has taken synthetics

3   without reaction, the intensivist is advised by the system that penicillin or cephalosporin may be

4   administered 1716. If the patient has reacted to synthetic or partially synthetic antibiotics, the

5   intensivist is next prompted to determine whether the patient needs penicillin or cephalosporin

6   specifically 1704.

7   If the patient is not required to have penicillin or cephalosporin, the intensivist is

8   prompted to administer the synthetic antibiotics 1706. If the patient does need penicillin or

9   cephalosporin, the intensivist is directed by the system to consider consulting with an allergist or

10   immunologist and perform skin tests for reactions 1708. Next, the intensivist is prompted to

11   enter whether the skin test was positive 1710. If the results are negative, the intensivist is further

12   directed by the system to administer penicillin or cephalosporin with caution, to consider

13   pretreatment with benadryl or prednisone to counter any reaction, and to closely monitor the

14   patient 1712. If the results of the skin test are positive, the intensivist is prompted by the system

15   to perform desensitization procedures 1714.

16   If the patient does not have a history suggestive of previous penicillin or cephalosporin

17   anaphylaxis 1700, the intensivist is prompted to determine whether the patient has previously

18   experienced skin-level reactions, such as exfoliative dermatitis, Stevens Johnson Syndrome, or

19   Toxic Epidermal Necrolysis, when given penicillin or cephalosporin 1718. If the patient has

20   previously experienced one of these reactions, the intensivist is directed by the system to

21   administer an alternative antibiotic 1720. If the patient has not experienced one of these

22   reactions, the intensivist is prompted to determine whether there is a history of any rash when

23   given penicillin or cephalosporin 1722. If the patent has not previously had a rash when given

1　penicillin or cephalosporin, the intensivist is advised that the patient will most likely be able to

2　take penicillin or cephalosporin **1724**.

3　　　If the patient has previously experienced a rash when given penicillin or cephalosporin,

4　the intensivist is prompted to determine whether the rash presented when the patient was given

5　ampicillin or amoxycillin **1726**. If the rash resulted from ampicillin or amoxycillin, the

6　intensivist is next prompted to determine whether the rash was urticarial **1728**. If the rash was

7　not urticarial, the intensivist is advised by the system that the patent probably can take penicillin

8　or cephalosporin, but should be closely monitored **1730**. If the rash was urticarial, the intensivist

9　is prompted to determine whether or not the patient needs penicillin or cephalosporin **1704**.

10　　　If the patient is not required to have penicillin or cephalosporin, the intensivist is directed

11　by the system to administer the synthetic antibiotics **1706**. If the patient does need penicillin or

12　cephalosporin, the intensivist is directed to consider consulting with an allergist or immunologist

13　and perform skin tests for reactions **1708**. Next, the intensivist is prompted to enter whether the

14　skin test was positive **1710**. If the results are negative, the intensivist is further directed to

15　administer penicillin or cephalosporin with caution, to consider pretreatment with benadryl or

16　prednisone to counter any reaction, and to closely monitor the patient **1712**. If the results of the

17　skin test are positive, the intensivist is directed to perform desensitization procedures **1714**.

18　　　Referring to **Figures 30A-B**, the Post-Op Hypertension decision support algorithm of the

19　present invention is illustrated. If an intensivist determines that there may be a possibility of

20　post-op hypertension, the intensivist may not be certain of all aspects that would be involved in

21　this particular condition. Therefore, the intensivist is lead through a decision support algorithm

22　which prompts the intensivist to determine the appropriate care to be given.

1   Initially, the intensivist is prompted to determine whether the patient is hypertensive (BP

2   greater than 20 percent above mean baseline) **1800**. If this criteria is met, the intensivist is

3   prompted to determine whether the patient has any of the causes of reversible hypertension: 1)

4   hypercapnia; 2) bladder distension; 3) pain; 4) increased ICP; 5) drugs (pressors, cocaine,

5   ketamine and chronic MAO use with indirect acting vasopressors); 6) automatic hyperreflexia; or

6   7) volume overload **1802**. If any of these criteria are met, the intensivist is prompted to first treat

7   those specific etiologies and, if pressure remains high, re-enter algorithm **1804**.

8   Alternatively, if none of these criteria are met **1802**, the intensivist is prompted to

9   determine whether the patient is at risk of injury from post-op hypertension (i.e., vascular

10   surgery, coronary artery disease, neurosurgery, ocular surgery, etc.) **1806**. If this criteria is not

11   met **1806**, the intensivist is prompted to determine whether the BP is greater than 40 percent

12   above mean baseline **1808**. If this criteria is not met, the intensivist is prompted that the patient

13   may not need BP treatment **1810**.

14   If the BP is greater than 40 percent above the mean baseline **1808**, the intensivist is

15   prompted to determine whether the patient is in pain **1812**. If this criteria is met **1812**, the

16   intensivist is prompted to treat pain and continue **1814**. Following this prompt **1814**, the

17   intensivist is prompted next to determine whether the patient is actively bleeding or at significant

18   risk for post-op bleeding (i.e., "moist closure" or high drain output) **1816**. If this criteria is met

19   **1816**, the intensivist is prompted to use only short acting agents including emolol and

20   nitroprusside as needed until bleeding has abated **1818**.

21   Alternatively, if this criteria is not met **1816**, the intensivist is prompted to determine

22   whether the patient is tachycardic (absolute greater than 90 bpm or ((relative greater than 15

23   percent over baseline)) **1820**. If this criteria is met **1820**, the intensivist is prompted to go to

1   Decision Table C, which is programmed for the condition of a high heart rate. If this criteria is

2   not met **1820**, the intensivist is prompted to eliminate (NOT C) Table C and proceed to the next

3   decision point **1820**.

HR↑ Table C							
	CAD	Y	Y	Y	N	N	N
	RAD	N	Y	Y	N	Y	N
	↓EF	N	N	Y	N	Y	Y
Treatment	1ST	L	E	L	L	A	E
	2ND	E	L	A	N	N	A

4

5   The intensivist is prompted next to determine whether the patient is bradycardic (absolute

6   less than 60 bpm) **1822**. If this criteria is met, the intensivist is prompted to go to Decision Table

7   B, which is programmed for the condition of a low heart rate.

HR↓ Table B							
	CAD	Y	Y	Y	N	N	N
	RAD	N	Y	Y	N	Y	N
	↓EF	N	N	Y	N	Y	Y
Treatment	1ST	N	N	A	N	A	A
	2ND	S	S	S	H	H	H

8

9   If this criteria is not met, the intensivist is prompted to eliminate (NOT B) Table B and

10   proceed to the next decision point **1822**. [Note: If NOT C and NOT B, the intensivist is

11   prompted to go to Table A by default, i.e., If NOT C and NOT B Then A].

HR (nl) Table A

		Y	Y	Y	N	N	N
	CAD	Y	Y	Y	N	N	N
	RAD	N	Y	Y	N	Y	N
	↓EF	N	N	Y	N	Y	Y
Treatment	1ˢᵗ	L	E	A	N	A	A
	2ᴺᴰ	N	N	E	A	N	N

1
2   The intensivist is prompted next to determine, sequentially, table input values for CAD,

3 RAD, and EF.

4   In these decision tables, the letter references have the following meanings: L=labetalol,

5 E=esmolol, A=enalapril, N=nicardipine, H=hyrdalazine, S=nitroprusside. The reference to 1ˢᵗ

6 and 2ⁿᵈ means that treatment should begin with the 1ˢᵗ drug and add or substitute the 2ⁿᵈ drug as

7 needed.

8   Using the above decision tables, the intensivist is prompted to determine whether the

9 patient has known coronary artery disease (CAD) or 3 or more risk factors for CAD **1824**. If this

10 criteria is met **1824**, the intensivist is prompted to enter a "Y" or "YES" for CAD into the table

11 selected above in **1820** and **1822**. If this criteria is not met, the intensivist is prompted to enter a

12 "N" or "NO" for CAD into the table selected above in **1820** and **1822**.

13   Next, the intensivist is prompted to determine whether the patient has known reactive

14 airway disease (RAD)**1826**. If this criteria is met **1826**, the intensivist is prompted to enter a "Y"

15 or "YES" for RAD into the table selected above in **1820** and **1822**. If this criteria is not met, the

16 intensivist is prompted to enter a "N" or "NO" for RAD into the table selected above in **1820** and

17 **1822**.

18   Next, the intensivist is prompted to determine whether the patient has known EF less than

19 30 percent or a history of systolic heart failure **1828**. If this criteria is met **1828**, the intensivist is

1 prompted to enter a "Y" or "YES" for EF into the table selected above in **1820** and **1822**. If this

2 criteria is not met **1828**, the intensivist is prompted to enter a "N" or "NO" for EF into the table

3 selected above in **1820** and **1822**.

4   Based on the table selected in **1820** and **1822** above, and the table inputs determined from

5 **1824**, **1826**, and **1828**, the intensivist is prompted with the proper medication to administer for

6 the 1st and 2nd treatment.

7   If the patient is not in pain **1812**, the intensivist is prompted to employ the procedures

8 described above in **1816**.

9   If the patient is at risk of injury from post-op hypertension **1806**, the intensivist is

10 prompted to determine whether the blood pressure is greater than 40 percent above baseline

11 **1830**. If this criteria is met **1830**, the intensivist is prompted to employ the procedures described

12 above in **1812**.

13   Alternatively, if this criteria is not met **1830**, the intensivist is prompted to determine

14 whether the patient is in pain **1836**. If this criteria is met **1836**, the intensivist is prompted to

15 treat pain and reevaluate following analgesia and, if still hypertensive, to continue algorithm

16 **1838**. Following this action **1838**, the intensivist is prompted to employ the procedures

17 described above in **1816**. If the patient is not in pain **1836**, the intensivist is prompted to employ

18 the procedures described above in **1816**.

19   If the patient is determined not to be hypertensive **1800**, the intensivist is prompted to

20 determine whether the patient requires their BP controlled near baseline (i.e., neurosurgery,

21 carotid surgery, thoracic aorta surgery) **1832**. If this criteria is not met **1832**, the intensivist is

22 prompted that the patient probably does not need treatment **1834**.

1   Alternatively, if this criteria is met **1832**, the intensivist is prompted to employ the

2 procedures described above in **1836**.

3   Referring to **Figure 31A**, the pulmonary embolism diagnosis algorithm is illustrated. If a

4 pulmonary embolism is suspected, the intensivist is first prompted to determine whether the

5 patient is hemodynamically unstable **2900**. If the patient is hemodynamically unstable, the

6 intensivist is directed by the system to consider performing an immediate transthoracic

7 echocardiogram, pulmonary angiogram and treatment consistent with massive pulmonary

8 embolism **2902**. If the patient is not hemodynamically unstable, the intensivist is prompted to

9 perform a VQ scan and perform further assessment of the patient **2904**.

10   In order to further assess the patient, the intensivist is prompted to respond to a series of

11 questions **2906, 2908, 2910, 2912**. The intensivist is prompted to determine whether any of the

12 following patient conditions are present: Dyspnea, Worsening chronic dyspnea, Pleuritic chest

13 pain, Chest pain that is non- retro sternal & non- pleuritic, O_2 saturation $< 92\%$ on room air that

14 corrects with 40% O_2 supplementation, Hemoptysis, or Pleural rub **2906**. The intensivist is also

15 prompted to determine whether any risk factors are in the patient's history, such as: Surgery

16 within 12 weeks, Immobilization (complete bed rest) for > 3 days within 4 weeks, Previous DVT

17 or objectively diagnosed PE, Lower extremity fracture & immobilization within 12 weeks,

18 Strong family history of DVT or PE(≥ 2 family members with objective proven events or 1st

19 degree relative with hereditary thrombophilia), Cancer (treatment within the last 6 months or

20 palliative stages), Postpartum, or Lower extremity paralysis **2908**. Further, the intensivist must

21 determine whether the patient has any of the following symptoms: Heart rate > 90 beats/min,

22 Temp ≥ 38.0, CXR free of abnormalities (edema, pneumonia, pneumothorax), or Leg symptoms

23 c/w DVT, syncope, blood pressure less than 90 mm Hg with heart rate greater than 100

1 beats/min, receiving mechanical ventilation and/or oxygen supplementation greater than 40%,

2 and new onset or right heart failure (-JVP, new S1, Q3, T3, or RBBB) **2910**. The intensivist is

3 also queried by the system to consider alternative diagnosis that may be more likely than

4 pulmonary embolism. To do so, the intensivist is prompted to consider conditions that simulate

5 major pulmonary embolism, such as myocardial infarction, acute infection with COPD, septic

6 Shock, dissecting aortic aneurysm, or occult hemorrhage. The intensivist is additionally

7 prompted to consider conditions that simulate minor pulmonary embolism, such as acute

8 bronchitis, pericarditis, viral pleurisy, pneumonia, and esophageal spasm **2912**.

9   Referring to **Figure 31BA**, the pulmonary embolism algorithm description continues.

10 The intensivist enters the answers to the assessment queries posed **2906, 2908, 2910, 2912** into

11 the system. If two or more responses to the patient condition query **2906** were answered yes and

12 one or more questions were answered yes from: Heart rate > 90 beats/min, Temp ≥ 38.0, CXR

13 free of abnormalities, or Leg symptoms c/w DVT of the symptoms query **2910** , the intensivist is

14 informed that a typical pulmonary embolism is present **2914**. Next, the system compares this

15 response to the answer to the alternative diagnosis query **2912**. If an alternative diagnosis is at

16 least as likely as pulmonary embolism **2916**, the intensivist is also given a low probability **2918**

17 to moderate probability **2920** risk factor. If an alternative diagnosis is less likely than pulmonary

18 embolism **2922**, the intensivist is given a moderate **2924** to high **2926** probability risk factor.

19   If less than two yes answers resulted from the patient conditions **2906**, the intensivist is

20 advised by the system that an atypical pulmonary embolism may be present **2928**. Next, the

21 system compares this response to the answer to the alternative diagnosis query **2912**. If an

22 alternative diagnosis is at least as likely as pulmonary embolism **2930**, the intensivist is told there

23 is no risk and low probability **2932** or some risk with a low probability **2934** risk factor. If an

1 alternative diagnosis is less likely than pulmonary embolism **2934**, the intensivist is given a no

2 risk and low probability **2938** to risk but moderate probability **2940.**

3   If at least one answer to the symptoms of syncope, blood pressure less than 90 mm Hg

4 with heart rate greater than 100 beats/min, receiving mechanical ventilation and/or oxygen

5 supplementation greater than 40%, and new onset or right heart failure **2910** is yes, the

6 intensivist is prompted with a message that severe pulmonary embolism is occurring **2942.** Next,

7 the system compares this response to the answer to the alternative diagnosis query **2912.** If an

8 alternative diagnosis is at least as likely as pulmonary embolism **2944**, the intensivist is told there

9 is a moderate probability of pulmonary embolism **2946.** If an alternative diagnosis is less likely

10 than pulmonary embolism **2948**, the intensivist is notified that a high probability of pulmonary

11 embolism is present **2950.**

12   Once the risk factors and probabilities are determined the system compares this

13 information to the VQ scan results. This comparison is performed according to the following

14 Table 4 below.

15 **Table 4: Probability table**

16
17 <u>**Input**</u>   <u>**Clinical Probability**</u>

18

V/Q Scan	High	Moderate	Low
High	A	A	B
Intermediate	B	C	C
Low	B	C	E
Normal	E	E	E

19
20
21 Where the VQ scan column and the risk column intersect, a letter code is assigned to various

treatment instructions. The treatment instructions are as follows.

A = Pulmonary embolus diagnosed. Begin treatment

E = Pulmonary embolus excluded

B = Proceed with the following work-up:
1) Perform spiral CT(If patient has renal insufficiency [creatinine > 2.0], consider going directly to pulmonary angiogram to reduce the potential dye load). If positive begin treatment,
2) If negative, assess for DVT using compression ultrasound or venography. If positive begin treatment,
3) If negative, perform pulmonary angiogram. If positive begin treatment, if negative diagnosis excluded.

C = Proceed with the following work-up:
1) Perform spiral CT. If positive begin treatment,
2) If negative, assess for DVT using compression ultrasound or venography. If positive begin treatment,
3) If negative perform D-dimer assay(elisa only). If negative diagnosis excluded, If positive, perform serial ultrasound of the lower extremities.

Once the correlation is made, the instructions associated with the letter code are displayed by the system to prompt the intensivist with diagnosis and treatment instructions.

Referring to **Figure 32**, the seizure decision support algorithm of the present invention is illustrated. If an intensivist encounters seizure in a patient, he may not be certain of all of the aspects and the timelines that are critical to treating this particular condition. Therefore, the intensivist is lead through a decision support algorithm, which divides the treatment sequence into three segments: 0-30 minutes; 30-60 minutes; and beyond 60 minutes.

At the onset of a seizure, in the 0-30 minute segment of the algorithm, the intensivist is prompted to give the patient lorazepam (0.1 mg/kg of bodyweight) in 2 mg boluses up to 8 mg 2000. Subsequently, the intensivist is prompted to give the patient phenytoin (18-20 mg/kg of bodyweight) at 50mg/min of fosphenytoin (18-20 mg/kg of bodyweight) at 150 mg/min followed by 5 mg/kg of bodyweight/day through separate IV line 2002.

During the 30-60 minute segment of the algorithm, the intensivist is prompted to: reload

additional phenytoin or fosphenytoin (10 mg/kg of bodyweight) maintaining previous infusion;

and give additional lorazepam (0.05 mg/kg of bodyweight) 2004. Subsequently, the intensivist is

prompted to begin continuous EEG monitoring 2006.

The intensivist is then prompted to determine whether the patient is hemodynamically

stable 2008. If hemodynamically stable, the intensivist is prompted to administer propofol 1-2

mg/kg of bodyweight bolus followed by 2-10 mg/kg/hr 2010.

At the 60 minute segment of the algorithm, the intensivist is prompted that if seizure

activity stops, he should taper either midazolam or propofol over the next 12-24 hours while

maintaining phenytoin but if seizures persist, he is prompted to move to the pentobarbital coma

block 2012.

Under pentobarbital coma, the intensivist is prompted to administer 10-15 mg/kg/hr and

to maintain until seizure control is achieved on EEG 2014. The intensivist is prompted further

that the patient usually requires PA catheter and pressors to maintain hemodynamic control 2014.

Alternatively, if the patient is determined to be hemodynamically unstable 2016, the

intensivist is prompted to utilize fluids and pressors as needed (phynylephrine or dopamine)

midazolam 0.2 mg/kg bolus followed by 0.1-2.0 mg/kg/hr 2018.

At the 60 minute segment of the algorithm, the intensivist is prompted that if seizure

activity stops, he should taper either midazolam or propofol over the next 12-24 hours while

maintain phenytoin but if seizures persist, he is prompted to move to the pentobarbital coma

block 2012.

Under pentobarbital coma, the intensivist is prompted to administer 10-15 mg/kg/hr and

to maintain until seizure control is achieved on EEG 2014. The intensivist is prompted further

1   that the patient usually requires PA catheter and pressors to maintain hemodynamic control **2014**.

2   Referring to **Figures 33A-B**, the supra ventricular tachycardia (SVT) decision support

3   algorithm of the present invention is illustrated. If an intensivist determines that SVT is present,

4   the intensivist may not be certain of all aspects that would be involved in treating this particular

5   condition. Therefore, the intensivist is lead through a decision support algorithm which prompts

6   the intensivist to determine the appropriate care to be given.

7   Initially, the intensivist is prompted to determine whether SVT is stable or unstable **2100**.

8   If SVT is stable **2102**, the intensivist is prompted to determine whether the patient has a regular

9   or irregular rhythm **2102**. If the patient has a regular rhythm **2104**, the intensivist is prompted to

10 determine whether there is a wide complex or a narrow complex **2104**. If the intensivist

11 determines that there is a wide complex **2106**, the intensivist is prompted to administer adenosine

12 6 mg/12 mg (if needed) **2108**. Following the administering of adenosine **2108**, the intensivist is

13 prompted to consider that if the patient converts to sinus rhythm (SR) to – consider re-entrant

14 junctional or WPW re-entrant. If the wide complex recurs, treat the patient with esmolol or

15 Ca+2 blockers.

16   Alternatively; if no effect, the intensivist is prompted to consider V-tach **2112**. Next, the

17 intensivist is prompted to: 1) load procainamide 150 mg over 10 min, then 1 mg/min infusion;

18 and 2) synchronized cardiovert **2114**.

19   Alternatively, if the wide complex slows, the intensivist is prompted to consider SVT w/

20 aberrancy and continue to slow with esmolol or Ca+2 blockers **2116**.

21   The intensivist is prompted next to administer esmolol/calcium blockers and link to

22 ventricular rate control **2118**. The intensivist is prompted next to determine whether there has

23 been a conversion to SR **2120**. If there is no conversion to SR in 24 hours, the intensivist is

1   prompted to add antiarrhythmic agent and consider anticoagulation **2122**. The intensivist is

2   prompted next to determine whether there has been conversion to SR. If conversion to SR, the

3   intensivist is prompted to continue maintenance antiarrhythmic agent during hospitalization

4   **2124**. If no conversion to SR, the intensivist is prompted to cardiovert while on antiarrhythmic

5   & following heparinization **2126**.

6   If the patient has a regular rhythm **2104**, the intensivist is prompted to determine whether

7   there is a wide complex or a narrow complex **2104**. If the intensivist determines that there is a

8   narrow complex **2128**, the intensivist is prompted to to administer adenosine 6mg/12mg (if

9   needed) **2130**. If administering the adenosine **2130** slows the ventricular rate only and the atrial

10   rate persists, the intensivist is prompted to consider atrial flutter and continue to slow with

11   esmolol or Ca+2 blockers **2132**. The intensivist is prompted next to employ the procedures

12   described above in **2118**.

13   If administering the adenosine **2130** converts the patient to SR, the intensivist is

14   prompted to consider re-entrant sinus or junctional and if recurs, treat with esmolol or Ca+2

15   blockers **2134**.

16   If administering the adenosine **2130** slows both atrial and ventricular rates the intensivist

17   is prompted that there is a probable sinus tachycardia **2136**. The intensivist is prompted next to

18   continue to slow with esmolol **2138**. The intensivist is prompted next to employ the procedures

19   described above in **2118**.

20   If SVT is stable **2102**, the intensivist is also prompted to determine whether the patient

21   has a regular or irregular rhythm **2102**. If the patient has an irregular rhythm **2140**, the

22   intensivist is prompted that if no p waves, there is probable Atrial fibrillation **2142**. The

23   intensivist is prompted next to slow ventricular response with esmolol or Ca+2 blockers **2144**.

1   The intensivist is prompted next to employ the procedures described above in **2118**.

2   If the patient has an irregular rhythm **2140**, the intensivist is prompted to determine

3   whether there are more than 3 p wave types MAT – and to treat underlying lung dz. and avoid

4   theophylline compounds **2146**. The intensivist is prompted next to slow rate with Ca+2 blockers

5   only **2148**. The intensivist is prompted next to employ the procedures described above in **2118**.

6   Referring now to **Fig. 33CA**, the description of the SVT decision algorithm continues. If

7   SVT is unstable **2101**, the intensivist is prompted to determine whether the patient has SBP less

8   than 80, ischemia, mental status changes **2150**. The intensivist is prompted next to perform

9   synchronous cardioversion (100 J, 200 J, 300 J) **2152**. The intensivist is prompted next that if

10   sinus rhythm: 1) correct reversible etiologies; 2) consider starting IV antiarrhythmic for

11   maintenance of sinus rhythm **2154**. Alternatively, following **2152**, the intensivist is prompted

12   next that if continued SVT: 1) correct reversible etiologies; 2) load IV antiarrhythmic (see dosing

13   guidelines) and repeat DC cardioversion **2156**.

14   For example, and without limitations, wide complex QRS Tachycardia is also addressed

15   in the decision support algorithm of the present invention. Referring to **Figures 34A-B**, the wide

16   complex QRS tachycardia decision support algorithm is illustrated. If an intensivist determines

17   that there may be a possibility of wide complex QRS tachycardia, the intensivist may not be

18   certain of all aspects that would be involved in this particular condition. Therefore, the

19   intensivist is lead through a decision support algorithm which prompts the intensivist to

20   determine the appropriate care to be given.

21   Initially, the intensivist is prompted to determine whether the patient is hemodynamically

22   stable (no angina, heart failure, or hypotension (systolic less than 80 mm)) **2200**. If this criteria

23   is not met, the intensivist is prompted to go to the cardio-pulmonary guidelines algorithm which

1 is generally known to those skilled in the art.

2 Alternatively, if this criteria is met, the intensivist is prompted to determine whether the

3 patient is within 7 days of a myocardial infarction or at risk for myocardial ischemia **2202**. If the

4 patient is not within 7 days of a myocardial infarction or at risk for myocardial ischemia **2202**,

5 the intensivist is prompted to determine whether the wide complex QRS rhythm is sustained

6 (greater than 30 seconds) **2234**. If this criteria is not met, the intensivist is prompted to

7 determined whether the QRS is monomorphic **2236**. If the QRS is monomorphic **2236**, the

8 intensivist is prompted to determine whether the patient has structural heart disease **2242**. If the

9 patient has structural heart disease **2242**, the intensivist is prompted to: 1) monitor closely; 2)

10 look for reversible etiologies; and 3) consider antiarrhythmic therapy **2244**. If the patient does

11 not have structural heart disease **2242**, the intensivist is prompted to: 1) monitor closely; 2) look

12 for reversible etiologies; and 3) if recurs and symptomatic may require further testing (prolonged

13 holter or EP study) **2246**.

14 If the QRS is not monomorphic **2236**, the intensivist is prompted to determine whether

15 the QT is prolonged **2238**. If this criteria is met, the intensivist is prompted to: 1) check K; 2)

16 give Mg; and 3) consider overdrive pacing **2240**. If the intensivist determines that the QT is not

17 prolonged, **2238**, the intensivist is prompted to employ the procedures described above in **2242**.

18 If the wide complex QRS rhythm is sustained **2234**, the intensivist is prompted to

19 determine whether the rhythm is polymorphic or irregular **2208**. If the rhythm is polymorphic or

20 irregular, the intensivist is prompted to consider atrial fibrillation with accessory pathway

21 conduction and load with procainamide and get a cardiology consultation **2210**. If the rhythm is

22 not polymorphic or irregular, the intensivist is prompted with the question of whether he wishes

23 to: 1) perform ECG diagnosis; or 2) administer adenosine diagnostically **2220**. If the intensivist

1 makes the determination to perform an ECG diagnosis **2220**, he is prompted to go to the ECG

2 diagnosis algorithm **2300**.

3 If the intensivist makes the determination to administer adenosine diagnostically **2220**, he

4 is prompted to go to the administer adenosine branch of the algorithm **2222**. If there is no effect,

5 the intensivist is prompted that there is probable VT and to determine whether the VT is

6 monomorphic **2224**. If the VT is monomorphic **2224**, the intensivist is prompted to load with

7 procainamide and perform synchronous cardioversion **2226**.

8 Alternatively, if the VT is not monomorphic **2224**, the intensivist is prompted to load

9 with lidocaine and perform immediate cardioversion **2228**.

10 If the ventricular response is slowed after administering adenosine **2222**, the intensivist is

11 prompted to consider SVT with aberrancy and treat with esmolol or Ca blockers **2230**.

12 If the ventricular response converts to sinus rhythm after administering adenosine **2222**,

13 the intensivist is prompted: to consider re-entrant mechanism with BBB or WPW; and, 1) if

14 WPW consult cardiology for possible ablation **2232**.

15 If the patient is within 7 days of a myocardial infarction or at risk for myocardial

16 ischemia **2202**, the intensivist is prompted to determine whether the wide complex is sustained

17 (30 seconds) **2204**. If the wide complex is not sustained **2204**, the intensivist is prompted to

18 determine whether the patient: 1) symptomatic; 2) tachycardia runs are frequent; or 3) the

19 tachycardia rates are rapid (greater than 180) **2212**. If this criteria is not met, the intensivist is

20 prompted to observe **2216**. Alternatively, if this criteria is met **2212**, the intensivist is prompted

21 to: 1) administer lidocaine 100-200 mg & 1-4 mg/min infusion; and 2) amiodarone **2214**.

22 If the wide complex is sustained **2204**, the intensivist is prompted to determine whether

23 the rate is greater than 140/min **2206**. If this criteria is not met **2206**, the intensivist is prompted:

1 to consider accelerated idioventricular, and that in some patients this can lead to hemodynamic

2 compromise; and that 1) he can perform overdrive pacing if needed 2218.

3 Alternatively, if this criteria is met, the intensivist is prompted to follow the procedures in

4 2208.

5 If the intensivist makes the determination to perform ECG Diagnosis 2220, he is

6 prompted to go to the ECG Diagnosis branch of the algorithm 2220. Referring now to Figure

7 34CA, in the ECG Diagnosis branch, the intensivist is prompted to determine whether the patient

8 has known pre-excitation syndrome 2300. If this criteria is met, the intensivist is prompted to

9 determine whether the QRS complexes are predominantly negative in leads V4-V6 2302. If the

10 QRS complexes are predominantly negative in leads V4-V6, the intensivist is prompted that

11 there is probable VT 2304.

12 If the QRS complexes are not predominantly negative in leads V4-V6 2302, the

13 intensivist is prompted to determine whether there is a QR complex in one or more of leads V2-

14 V6 2306. If this criteria is met, the intensivist is prompted that there is probable VT 2308.

15 Alternatively, if this criteria is not met 2306, the intensivist is prompted to determine

16 whether there are more QRS complexes than P waves 2310. If there are more QRS complexes

17 than P waves 2310, the intensivist is prompted that there is probable VT 2312. If there are not

18 more QRS complexes than P waves 2310, the intensivist is prompted: to consider pre-excited

19 SVT; and that he may wish to perform EP study 2314.

20 If the intensivist determines that the patient does not have known pre-excitation

21 syndrome 2300, the intensivist is prompted to determine whether there is an RS complex present

22 in any precordial lead 2316. If this criteria is not met 2316, the intensivist is prompted that there

23 is probable VT 2318.

1   Alternatively, if this criteria is met 2316, the intensivist is prompted to determine whether

2   the R to S interval is greater than 100 MS in any one precordial lead 2320. If this criteria is met,

3   the intensivist is prompted that there is probable VT 2322.

4   If the R to S interval is not greater than 100 MS in any one precordial lead 2320, the

5   intensivist is prompted to determine whether there is evidence of atrioventricular dissociation

6   2324. If this criteria is met, the intensivist is prompted that there is probable VT 2326.

7   Alternatively, if there is no evidence of atrioventricular dissociation 2324, the intensivist

8   is prompted to determine whether V-1 is negative and V-6 positive and QRS greater than 0.14

9   mSEC 2328. If this criteria is met, the intensivist is prompted that there is probable VT 2330.

10   If this criteria is not met 2328, the intensivist is prompted that the situation may represent

11   SVT with aberrancy or underlying bundle branch block 2332.

12   Referring to **Figure 35A**, the assessment of sedation algorithm of the present invention is

13   illustrated. If an intensivist encounters a need for sedation, he may not be certain of all of the

14   aspects and the timelines that are critical to this particular process. Therefore, the intensivist is

15   lead through a decision support algorithm, which prompts the intensivist to address a number of

16   factors in the process 3100.

17   The intensivist is prompted initially to go to the Scoring section of the algorithm 3100.

18   The intensivist is prompted to proceed through a number of scorings 3102 and to first score the

19   patient's alertness with points being allocated in the following manner: asleep/unresponsive=0;

20   responsive to voice=1; and hyperresponsive=2 3104.

21   The intensivist is prompted next to score the patient's movement with points being

22   allocated in the following manner: no spontaneous movement=0; spontaneous movement=1; and

23   pulls at lines, tubes, dressings=2 3106.

1   The intensivist is prompted next to score the patient's respiration based on whether the

2   patient is mechanically ventilated or spontaneously breathing with points being allocated as

3   subsequently discussed. If the patient is mechanically ventilated, the intensivist is prompted to

4   allocate points in the following manner: no spontaneous ventilation=0; spontaneous ventilations

5   and synchronous with ventilator=1; or spontaneous ventilations with cough or dysynchrony>10

6   percent of breaths=2 **3108**. Alternatively, if the patient is spontaneously breathing, the

7   intensivist is prompted to allocate points in the following manner: respiration rate (RR) <10=0;

8   RR=10-30=1; or RR>30=2 **3108**.

9   The intensivist is prompted next to score the patient's heart rate with points being

10   allocated in the following manner: >20 percent below mean for last 4 hr=0; within 20 percent

11   mean for last 4 hr=1; or >20 percent above mean for last 4 hr=2 **3110**.

12   The intensivist is prompted next to score the patient's blood pressure with points being

13   allocated in the following manner: MAP >20 percent for last 4 hr=0; MAP within 20 percent

14   mean for last 4 hr=1; or MAP >20 percent above mean for last 4 hr=2 **3112**.

15   The intensivist is prompted next to determine the sedation score by the following

16   formula: SEDATION SCORE=alertness + movement + respirations + heart rate + blood

17   pressure **3114**. In one embodiment, respiratory rate, heart rate, and BP can be computer linked to

18   monitor data thereby simplifying the sedation scoring assessment. The nursing observations are

19   deemed intuitive and the nursing burden in sedation scoring can be minimal by using this point

20   scoring.

21   Referring now to **Figure 35BA**, the sedation assessment algorithm description continues.

22   The intensivist is prompted then to continue the sedation assessment by moving to the Pain

23   Assessment section of the algorithm **3116**.

In the Pain Assessment section, the intensivist is prompted to determine whether the patient is conscious, communicative, and acknowledging pain **3118**. If this criteria is not met, the intensivist is prompted to determine: whether the sedation score is greater than 2 and the patient: is known to be in pain before becoming uncommunicative; or S/p recent surgery; or having tissue ischemia or infarct; or has wounds; or has large tumor possibly impinging on nerves. If the answer to either of these two questions is YES, the intensivist is prompted to treat for pain **3118**. The intensivist is prompted then to continue the assessment by moving to the Delirium Assessment section of the algorithm **3118**.

In the Delirium Assessment section, the intensivist is prompted to determine whether the sedation score is greater than 2 AND the patient has: day/night reversal with increased agitation at night OR eyes open and "awake" but disoriented; or eyes open and "awake" but pulling at lines, tubes, or dressings OR difficult to sedate prior to ventilator weaning OR paradoxical response to benzodiazepines. If this criteria is met, the intensivist is prompted to consider butyrophenone **3120**.

Referring to **Figure 36**, the Bolus sliding scale algorithm is illustrated. If an intensivist encounters a need for sedation, the algorithm for which may contain a reference to the bolus sliding scale for midazolam, he may not be certain of all of the aspects which are critical to this scale. Therefore, the intensivist is lead through a decision support algorithm, which prompts the intensivist through the use of the scale **3200**.

If lorazepam is less than 0-2 mg IV q 6hr, then the intensivist is prompted to give midazolam 1-2 mg q 5 min until adequately sedated **3202**.

Alternatively, if lorazepam equals 2-4 mg IV q 4 hr, then the intensivist is prompted to give midazolam 2 mg q 5 min until adequately sedated **3202**.

1   Alternatively, if lorazapam is greater than 10 mg IV q 4 hr, then the intensivist is

2   prompted to give midazolam 5 mg q 5 min until adequately AND consider fentanyl and/or

3   droperidol or Haldol for synergy despite delirium and pain assessment 3202.

4   Yet another decision support routine is the sedation algorithm. Referring to **Figure 37,**

5   the sedation process decision support algorithm is illustrated. If an intensivist determines that a

6   patient will require sedation, the intensivist may not be certain of all aspects that would be

7   involved in this particular process. Therefore, the intensivist is lead through a decision support

8   algorithm, which prompts the intensivist to conduct a sedation assessment based on: 1) scoring;

9   2) pain; and 3) delirium (see Assessment of Sedation algorithm) **3300.**

10   Following completion of the sedation assessment process **3300,** the intensivist is

11   prompted to determine whether the patient is in pain **3302.** If this criteria is met, the intensivist

12   is prompted to administer bolus morphine, fentanyl, other narcotic, start patient controlled

13   analgesic (PCA) or epidural analgesia as indicated **3324.** If the patient is not in pain **3302** or

14   after administering bolus morphine, fentanyl, other narcotic, start patient controlled analgesic

15   (PCA) or epidural analgesia as indicated **3324,** the intensivist is prompted to determine whether

16   the patient is delirious **3304.**

17   If the intensivist determines that the patient is delirious **3304,** he is prompted to

18   administer droperidol 2.5-5 mg q30min prn and that he may consider IV Haldol not to exceed

19   30mg/24hr **3326.** If the patient is not delirious or after following the procedures in **3326,** the

20   intensivist is prompted to determine whether the patient will need sedation for more than the next

21   24 hours **3306.** If the patient will not need sedation for more than the next 24 hours **3306,** the

22   process continues as described in **Figure 38.**

23   Alternatively, if the patient will need sedation for more than the next 24 hours **3306,** the

1   intensivist is prompted to determine whether the sedation score is 8-10 **3308**. If this criteria is

2   met, the intensivist is prompted to employ the Bolus sliding scale midazolam and increase

3   lorazepam by 20 percent **3328** (see Bolus sliding scale midazolam algorithm – **Figure 36**).

4   Subsequently, the intensivist is prompted to reassess sedation in 4 hr **3330**.

5   If the sedation score is not 8-10, the intensivist is prompted to determine whether the

6   sedation score is greater than or equal to the last Sed Scr after sedative bolus or increase **3310**. If

7   this criteria is met, the intensivist is prompted to employ the procedures described above in **3328**

8   and **3330**.

9   If the sedation score is not greater than or equal to the last Sed Scr after sedative bolus or

10   increase **3310**, the intensivist is prompted to determine whether four (4) or more midaz boluses

11   have been given since last q4hr assessment **3312**. If this criteria is met, the intensivist is

12   prompted to employ the procedures described above in **3328** and **3330**.

13   Alternatively, if less than four (4) midaz boluses have been given since last q4hr

14   assessment **3312**, the intensivist is prompted to determine whether the patient is adequately

15   sedated **3314**. If this criteria is not met, the intensivist is prompted to employ the procedure

16   described in **3328** and **3330**.

17   If the intensivist determines that the patient is adequately sedated **3314**, the intensivist is

18   prompted to determine whether the sedation score is 0-2 **3316**. If this criteria is met, the

19   intensivist is prompted to decrease lorazepam by 20 percent **3332** and reassess sedation in 4 hr

20   **3334**.

21   Alternatively, if the sedation score is not 0-2 **3316**, the intensivist is prompted to

22   determine whether the sedation score is less than or equal to the last Sed Scr after sedative

23   decrease **3318**. If this criteria is met, the intensivist is prompted to employ the procedure

1   described in 3332 and 3334.

2   If the sedation score is not less than or equal to the last Sec Scr after sedative increase

3   3318, the intensivist is prompted to determine whether the patient is clinically oversedated 3320.

4   If the patient is clinically oversedated 3320, the intensivist is prompted to employ the procedure

5   described in 3332 and 3334. If the patient is not clinically oversedated 3320, the intensivist is

6   prompted to reassess sedation in 4 hr 3322.

7   Referring to **Figure 38**, the short term sedation process decision support algorithm of the

8   present invention is illustrated. If an intensivist determines that a patient will not require

9   sedation past the next 24 hour period, the intensivist may not be certain of all aspects that would

10   be involved in this particular process. Therefore, the intensivist is lead through a decision

11   support algorithm, which prompts the intensivist to conduct a sedation assessment based on: 1)

12   scoring; 2) pain; and 3) delirium (see Assessment of Sedation algorithm) **3100**.

13   Following completion of the sedation assessment process **3100**, the intensivist is

14   prompted to decrease lorazepam by 20 percent from baseline per day **3102**. The intensivist is

15   prompted next to determine whether the patient is in pain **3104**. If this criteria is met, the

16   intensivist is prompted to administer bolus morphine or fentanyl **3122**. If the patient is not in

17   pain or after administering bolus morphine or fentanyl **3122**, the intensivist is prompted to

18   determine whether the patient is delirious **3106**.

19   If the intensivist determines that the patient is delirious, he is prompted to administer

20   droperidol 2.5-5 mg q30min prn **3124**. If the patient is not delirious or after administering

21   droperidol **3124**, the intensivist is prompted to determine whether the sedation score is 8-10

22   **3108**.

23   If this criteria is met, the intensivist is prompted to employ the Bolus sliding scale

1   midazolam (see Bolus sliding scale midazolam algorithm) and begin midazolam infusion or

2   begin propofol 1-2 mg/kg bolus and 5-50 mcg/kg/min infusion 3126. Subsequently, the

3   intensivist is prompted to reassess sedation in 1 hr 3128.

4   If the sedation score is not 8-10, the intensivist is prompted to determine whether the

5   sedation score is greater than or equal to the last Sed Scr after sedative bolus or increase 3110. If

6   this criteria is met, the intensivist is prompted to employ the procedures described above in 3126

7   and 3128.

8   If the intensivist determines that the sedation score is not greater than the last sedation

9   score after sedative bolus or increase 3110, the intensivist is prompted to determine whether the

10   patient is adequately sedated 3112. If this criteria is not met, the intensivist is prompted to

11   employ the procedures described above in 3126 and 3128.

12   If the intensivist determines that the patient is adequately sedated 3112, he is prompted to

13   determine whether the sedation score is 0-2 3114. If this criteria is met, the intensivist is

14   prompted to determine if the patient has been sedated for more than 72 hours 3130. If the

15   patient has not been sedated for more than 72 hours 3130, the intensivist is prompted to hold

16   midazolam or propofol and hold or decrease lorazepam by 50 percent 3132. The intensivist is

17   prompted subsequently to reassess sedation in 1 hour 3134.

18   Alternatively, if the intensivist determines that the patient has been sedated for more than

19   72 hours 3130, the intensivist is prompted to hold midazolam or propofol and decrease

20   lorazepam by 20 percent per day 3136. The intensivist is prompted subsequently to reassess

21   sedation in 1 hour 3134.

22   Alternatively, if the intensivist determines that the sedation score is not 0-2 3114,

23   the intensivist is prompted to determine whether the sedation score is less than or equal to the

1   last sedation screening after sedative decrease **3116**. If this criteria is met, the intensivist is

2   prompted to determine whether the patient has been sedated for more than 72 hours and to

3   follow the procedures described above in **3130**.

4   If the intensivist determines that the sedation score is not less than or equal to the

5   last Sed Scr after sedative decrease **3116**, the intensivist is prompted to determine whether the

6   patient is clinically oversedated **3118**. If this criteria is met, the intensivist is prompted to

7   determine whether the patient has been sedated for more than 72 hours and to follow the

8   procedures described above in **3130**. If this criteria is not met, the intensivist is prompted to

9   reassess sedation in 1 hr **3120**.

10   Referring to **Figure 39**, the respiratory isolation decision support algorithm is illustrated.

11   If an intensivist determines that there may be a need for respiratory isolation, the intensivist may

12   not be certain of all aspects that would be involved in this process. Therefore, the intensivist is

13   lead through a decision support algorithm which prompts the intensivist to determine the need

14   for respiratory isolation based upon: a) clinical assessment; and/or b) smear/culture findings

15   **3500**.

16   Pursuing the clinical assessment branch of the decision support algorithm, the intensivist

17   is prompted to determine whether the patient has known mTB (mycobacterium tuberculosis)

18   **3502**. If this criteria is met, the intensivist is prompted to determine whether the patient has been

19   compliant with their medications for over 2 weeks and is clinically responding **3512**. If the

20   patient has not been compliant with their medications for over 2 weeks and is not clinically

21   responding **3512**, the intensivist is prompted that isolation is required **3514**. If the patient has

22   been compliant with their medications and is clinically responding **3512**, the intensivist is

23   prompted that no isolation is required **3516**.

Alternatively, if the patient does not have known mTB 3502, the intensivist is prompted to determine whether the patient has known mycobacterial disease other than TB 3504. If this criteria is met, the intensivist is prompted to determine whether the patient has new CXR (chest x ray) findings and symptoms (cough 2 weeks, fever, weight loss) 3518. If the patient does not have new CXR findings and symptoms 3518, the intensivist is prompted that no isolation is required 3520. If the patient does have new CXR findings and symptoms 3518, the intensivist is prompted that isolation is required 3522.

If the patient does not have known mycobacterial disease other than TB 3504, the intensivist is prompted to determine whether there is a new cavitary lesion on CXR 3506. If this criteria is met, the intensivist is prompted that isolation is required 3524.

Alternatively, if there is no new cavitary lesion on CXR 3506, the intensivist is prompted to determine whether there are pulmonary infiltrates or whether the patient is HIV (human immunodeficiency virus) positive 3508. If this criteria is not met, the intensivist is prompted that no isolation is required 3510. If this criteria is met, the intensivist is prompted to determine whether the patient has new CXR findings and symptoms (cough 2 weeks, fever, weight loss) and at high risk: 1) known mTB exposure; 2) homeless; 3) prisoner; 4) travel to area with multi-drug resistant TB 3526. If this criteria is met, the intensivist is prompted that isolation is required 3528. Alternatively, if this criteria is not met, the intensivist is prompted that no isolation is required 3530.

Pursuing the smear/culture branch of the decision support algorithm 3500, the intensivist is prompted to determine whether the AFB (acid-fast bacilli) smear is positive 3532. If the AFB smear is not positive, the intensivist is prompted that: no isolation is required; await culture results; if culture negative, no isolation required; if culture positive and patient has mycobacterial

1   disease other than TB (MOTT no isolation is required; if the culture is positive and the patient

2   does not have MOTT consult ID **3534**.

3   Alternatively, if the AFB smear is positive, the intensivist is prompted to determine

4   whether the patient has known mycobacterial disease other than TB **3536**. If this criteria is not

5   met, the intensivist is prompted that isolation is required **3538**. If this criteria is met, the

6   intensivist is prompted: to isolate until results of NAP test are in; if mTB positive isolate the

7   patient; if no mTB, no isolation is required **3540**.

8   Referring to **Figure 40**, the empiric meningitis treatment decision support algorithm of

9   the present invention is illustrated. If the intensivist is treating a patient for meningitis, the

10   intensivist is prompted to answer a series of queries by the system to properly address

11   medication and dosage. First, the intensivist is prompted to determine whether the patient has

12   suffered a head trauma or undergone neurosurgery **3700**. The answer to this question is input 1

13   to **table x** below. The intensivist is next prompted to determine whether the patient is allergic to

14   penicillin or is from an area where penicillin resistant staphylococcus pneumoniae is prevalent

15   **3702**. The answer to this question becomes input 2 to **table x** below. The intensivist must also

16   determine whether the patient is immunocompromised **3704**, and the answer becomes input 3 to

17   **table x** below. The intensivist determines if the patient is over fifty years of age **3706**, with the

18   answer being input 4 in **table x** below. Lastly, the intensivist is prompted to determine whether

19   the patient has altered mental status **3708**, and the answer becomes input 5 in **table x** below. The

20   inputs to each of these prompts **3702, 3704, 3706, 3708** is compared to a dosage database

21   according to the **Table 5** below.

22   **Table 5**: Meningitis Input-Output Table

Input	Combinations	Output
1	1 = yes	A) vancomycin

	2 = no	1.5 – 2 gm IV q 12h + ceftazedine 2gm IV q 8 hr or cefapime 2gm IV q 8 hr
2	1 = yes 2 = no	B) vancomycin 1.5 – 2 gm IV q 12h + aztreonam 0.5 – 2 gm IV q 6-8 hr
3	1 = no 2 = no 3 = no 4 = yes	**ampicillin 2 gm IV q 4h** + ceftriaxone 2 gm IV q12 cefotaxime 2 gm IV q 6 h
4	1 = no 2 = no 3 = no 4 = no	**ceftriaxone 2 gm IV q 12 hr** or cefotaxime 2 gm IV q 6 hr
5	1 = no 2 = no 3 = yes	**ampicillin 2 gm IV q 4 hr** + ceftazidime 2 gm IV q 8 hr or cefipime 2 gm IV q 8 hr
6	1 = no 2 = yes 3 = no 4 = yes	**vancomycin 1.5 – 2 gm IV q 12 hr** + chloramphenicol 1 gm IV q 6 hr
7	1 = no 2 = yes 3 = no 4 = no	
8	1 = no 2 = yes 3 = yes	
9	5 = yes to inputs 3-8	add to output consider acyclovir 10 mg/kg IV q 8h

In the Meningitis Input-Output Table, possible combinations of the five inputs are listed.
For the conditions manifested in the patient, different drugs and dosages will be required. The
proper treatment for each combination is listed in the output column of **Table x**. After the
algorithm runs the comparison, the output is displayed on the computer screen, prompting the
intensivist with the proper treatment 3712.

Referring to **Figure 41A**, the ventilator weaning decision support algorithm of the

1   present invention is illustrated. The ventilator weaning decision support algorithm is used to

2   determine whether an intensive care unit patient can return to breathing unassisted, and

3   discontinue use of a ventilator. Such a determination requires evaluation of the patient by the

4   intensivist over the course of several days.

5   To begin the decision process of whether to wean a patient from ventilator use, the

6   intensivist is prompted to conduct daily screening, preferably during the hours of 06:00 a.m. to

7   10:00 a.m 3800. The daily screen prompts the intensivist to determine whether: the patients P/F

8   ratio is greater than 200, the patient's positive end-expiratory pressure (PEEP) is less than or

9   equal to 5, whether cough suctioning has been adequate and/or spontaneous, infusions with

10 vasopressors have been necessary, and continuous infusions of sedatives or neuromuscular

11 blocking agents have been necessary 3800. If all conditions 3802 are answered no, the

12 intensivist is directed by the system to repeat the daily screen 3805 the following morning. If all

13 the conditions of the daily screen are met 3802, the intensivist is prompted to perform additional

14 tests.

15 If the patient has satisfied the daily screen, the intensivist is next directed to conduct a

16 rapid shallow breathing test 3804. To perform the test, the intensivist is directed to change the

17 ventilator setting to continuous positive airway pressure (CPAP) less than or equal to 5. In other

18 words, there is no intermittent mandatory ventilation or pressure support provided for the patient.

19 The patient is given one minute to reach a steady state of breathing. Then the intensivist

20 measures the ratio of breaths per minute to tidal volume (f/V_T). The intensivist next is prompted

21 to determine whether the patient's f/V_T is less than or equal to 105 breathes per minute 3806. If

22 the patient's f/V_T is greater than 105 breathes per minute, the intensivist is prompted to return to

23 performing daily screening the following morning 3808.

If the patient's f/V_T is less than or equal to 105 breathes per minute, the intensivist is next directed to perform a trial of spontaneous breathing. Here, the intensivist can either insert a T-Piece in the patient's airway or reduce the patient's CPAP to less than or equal to 5 over the course of two hours. The intensivist is prompted to observe the patient periodically in order to evaluate if the patient is breathing without assistance 3810. The intensivist is prompted to perform a periodic assessment by determining whether: the patient's breathing characteristics are greater than 35 breaths per minute for 5 minutes, or SpO_2 is less than 90%, or the patient's Heart Rate (HR) is grater than 140, or HR deviates from the baseline breathing rate by more than 20%, or the patient's SBP is outside the range of 90 to 180. If any of the conditions are met, the intensivist is directed by the system to terminate ventilator weaning 3812. If the conditions are not met, the patient is further assessed.

In further assessment, the intensivist is prompted to determine whether the patient has been able to breathe spontaneously for two hours, keep a clear airway, and does not have any procedures scheduled within twenty-four hours that would require the patient to be intubated 3814. If the patient meets all of these criteria 3814, the intensivist is notified by the system that the patient may be extubated 3816. If the patient does not meet one or more of the criteria 3814, the intensivist is prompted to perform steps for progressive weaning 3818.

Referring to **Figure 41BA**, the ventilator weaning decision support algorithm of the present invention is further illustrated. The intensivist, at his or her discretion may choose either T-piece progressive weaning or pressure support progressive weaning. In order to perform T-piece progressive weaning, the intensivist is directed to repeat the trial of spontaneous breathing (as previously described 3810). The intensivist can either insert a T-piece in the patient's airway or reduce the patient's CPAP to less than or equal to 5 over the course of two

96

1   hours. The intensivist is prompted to perform periodic assessment of the patient by either a two

2   hour or 30 minute trial **3820**.

3   In order to perform pressure support progressive weaning, the intensivist is first prompted

4   to observe whether the patient's pressure support (PS) rating is equal to eighteen plus or minus

5   the positive end-expiratory pressure (PEEP). Next, the intensivist is directed by the system to

6   regulate the pressure values in order to keep the patient's respiratory rate (RR) between twenty

7   and thirty. Next, the intensivist is directed by the system to decrease the patient's pressure

8   support by 2-4 centimeters of water two times per day. Once the patient maintains pressure

9   support for at least two hours, the intensivist is prompted to further pursue extubating the patient

10   **3822**.

11   After either T-Piece progressive weaning **3820** or pressure support progressive weaning

12   **3822**, the intensivist is next prompted to perform a periodic assessment of the patient. Here, the

13   intensivist must determine whether whether: the patient's breathing characteristics are greater

14   than 35 breaths per minute for 5 minutes, or SpO_2 is less than 90%, or the patient's HR is grater

15   than 140, or HR deviates from the baseline breathing rate by more than 20%, or the patient's

16   SBP is outside the range of 90 to 180. Where the patient meets any of these criteria, the

17   intensivist is prompted to terminate weaning. If the patient meets none of these criteria, the

18   intensivist is prompted to further assess the patient's ability to breath spontaneously **3824**.

19   In further assessment, the intensivist is prompted to determine whether the patient has

20   been able to breathe spontaneously for two hours, keep a clear airway, and does not have any

21   procedures scheduled within twenty-four hours that would require the patient to be intubated

22   **3826**. If the patient meets all of these criteria **3814**, the intensivist is notified by the system that

23   the patient may be extubated **3828**. If the patient does not meet one or more of the criteria **3826**,

97

1   the intensivist is directed by the system to allow the patient to rest for at least twelve hours at

2   A/C, the last level of pressure support the patient achieved **3830**. The intensivist is prompted to

3   resume progressive weaning the following day **3832**.

4   Referring to **Figure 42**, the Warfarin Dosing Algorithm of the present invention is

5   illustrated. The intensivist is first prompted to give the initial dose and determine subsequent

6   dosage each day **3900**. When the intensivist determines subsequent dosage, he is first prompted

7   to determine the patient's target INR **3902**. If the patient's target INR ranges from 2.0 to 3.0, the

8   intensivist is prompted by the system to make further determinations relevant to dosage. The

9   intensivist is directed by the system to determine whether the patient is taking drugs that effect

10 prothrombin time **3904**, the baseline INR value **3906**, and whether rapid anticoagulation is

11 required **3908**. Each answer is assigned a point value, and the total points are tabulated. If the

12 point value is greater than one, the system refers to the 10 milligram load target database for

13 dosing. If the point value is less than one, the system refers to the 5 milligram load target

14 database for dosing **3910**.

15   At the initial INR determination **3902**, if the patient's INR was initially between 1.5 and

16 2.0, the system refers to the 5 milligram load target database for dosing. If the patient's INR was

17 initially between 3.0 and 4.0, the system refers to the 10 milligram load target database for

18 dosing **3910**. Next the intensivist is prompted to enter the day of treatment **3912** and the

19 patient's INR **3914**. Depending on whether the system has been directed to the 5 milligram load

20 target or the 10 milligram load target, a comparison is run **3916** according to the following

21 tables.

22

23   **5 mg Load Target INR 1.5-2.0**
24

Day	<1.5	1.5-2	2-2.5	>2.5
2	5	1.25 - 2.5	0	0
3	5-7.5	1.25 - 2.5	0 - 1.25	0
4	10– (Check to see whether pt has received vit K)	1.25 - 2.5	0 - 1.25	0
5	10 (Check to see whether pt Has received vit K)	2.5 - 5	0 - 2.5	0 - 1.25
6	15 Obtain hematology consultation.	2.5 - 5	1.25 - 2.5	0 - 1.25

1
2
3 **10 mg Load Target INR 3.0-4.0**

Day	<1.5	1.5-2	2-2.5	2.5-3	>3
2	10	7.5 - 10	5-7.5	2.5-5.0	0-2.5
3	10 -15	7.5 - 10	5-7.5	2.5 - 5	2.5-5
4	10 -15 (Check to see whether pt has received vit K)	7.5 -12.5	5 – 10	5-7.5	2.5-5
5	15 (Check to see whether pt has received vit K)	10 – 12.5	7.5-10	5 – 7.5	2.5-5
6	15-20 obtain hematology consultation.	10 - 15	7.5-12.5	5 - 10	5-7.5

4
5
6 The appropriate dosage and instructions is displayed on the computer screen to the intensivist
7 **3918**.
8   Referring to **Figure 438**, the heparin-induced thrombocytopenia (HIT) decision support

9 algorithm of the present invention is illustrated.   The intensivist is prompted to observe whether

10 the patient's platelet count has dropped 50% or more over seventy-two hours while being treated

1   with heparin, and whether any other obvious causes of platelet reduction might be present **4100**.

2   If such a drop has not occurred, the intensivist is notified by the system that the patient most

3   likely does not have HIT, but monitoring of the platelet count should continue **4102**. If the

4   patient's platelet count has drastically dropped, the intensivist is prompted to determine whether

5   the patient has been treated with heparin for more than three days **4104**. Regardless of the

6   answer, the intensivist is next prompted to determine if the patient has been treated with heparin

7   in the preceeding three months **4106**. If the patient has not received heparin in the preceeding

8   three months, the intensivist is notified by the system that HIT is not likely to be the cause of the

9   platelet drop. The intensivist is also prompted to monitor platelet count for infection or other

10   thronbocytopenia-causing drugs, and to consider stopping heparin therapy if the platelet count

11   drops below 50,000 per cubic millimeter **4108**.

12   If the patient has received heparin in the last three days **4104**, the intensivist is further

13   prompted to look for signs of thrombosis, or blood clotting **4110**. If the patient shows signs of

14   thrombosis, the intensivist is notified by the system that the patient is likely to have HIT.

15   Accordingly, the intensivist is prompted to stop administering heparin and flush any drug

16   administration equipment that would contain heparin traces. The intensivist is also provided

17   instructions by the system to treat a patient still requiring anticoagulation treatment with alternate

18   drugs and methods **4112**.

19   Where the patient does not show signs of thrombosis **4110**, the intensivist is prompted to

20   check for heparin resistance **4114**. Signs of heparin resistance include inability to hold aPTT

21   though heparin doses have been increase. If the patient shows signs of heparin resistance, the

22   intensivist is prompted to consider stopping heparin treatment and to consider treating a patient

23   still requiring anticoagulation treatment with alternate drugs and methods **4116**. If the patient

1 does not show signs of heparin resistance, the intensivist is notified by the system that the patient

2 possibly has HIT. The intensivist is accordingly prompted to continue monitoring for

3 thrombosis, consider infection or other drugs that cause throbocytopenia, and to consider

4 stopping heparin therapy if the platelet count drops below 50,000 per cubic millimeter **4118**

5 **Results**

6   The structure of the present invention and its efficacy have yielded striking results in

7 practice. In a research setting, deployment of certain rudimentary aspects of the present the

8 invention designed to experimentally test the approach described and developed in detail above,

9 yielded unprecedented improvements in clinical and economic outcomes: 50% improvement in

10 severity adjusted mortality, 40% improvement in clinical complication rates, 30% improvement

11 in ICU length of stay, and 30% improvement in overall ICU cost of care.

12   A system and method of remote monitoring of ICU's and other healthcare locations has

13 been shown. It will be apparent to those skilled in the art that other variations of the present

14 invention are possible without departing from the scope of the invention as disclosed. For

15 example, one can envision different ratios of command center/remote location to ICU's, other

16 decision support algorithms that would be used by intensivists, other types of remote monitoring

17 of not only ICU's but other types of hospital functions as well as industrial functions where

18 critical expertise is in limited supply but where that expertise must be applied to ongoing

19 processes. In such cases a system such as that described can be employed to monitor processes

20 and to provide standardized interventions across a number of geographically dispersed locations

21 and operations.

22